EPA Reg. No. 68451-1 Vol. 1



Date of Application	ACTION CODE	RECORD NO./	EVENT	RESPONSE RESPONSE CODE	
8-11-93	165		Day dota Submitted u/3/2000	11-6-98 37	
8-22-95	166	49 4860		5-2-96 16	
8-21-95	166	1.494967		5-2-96 16	
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AUG 2 U 2003

Ms. Mary K. Hagler, MS Regulatory Specialist - Pharmaceuticals Intervet, Inc 405 State Street, P.O. Box 318 Millsboro, DE 19966

Subject:

Amendment - Revised First Aid Statements

Deltamethrin 4% Collar

EPA Registration No. 68451-1

Your Submission Dated May 20, 2003

Dear Ms. Hagler:

The amendment referred to above, submitted in connection with registration under section 3 (c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable, subject to the comments listed below.

Under the "Precautionary Statements" section, move the statements "Do not open...with this collar" and the paragraph beginning "Do not use on puppies under . . .etc" to the "Directions for Use" section of your label.

A stamped copy of the label is enclosed for your records. If you have any questions, please call Dr. William Sproat of my team at 703-308-8587.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide Branch Registration Division (7505C)

Enclosure

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Kills Fleas and Ticks for up to 6 Months
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (including deer ticks which may carry Lyme disease)
ALSO KILLS FLEAS

ACTIVE INGREDIENT: Deltamethrin

INERT INGREDIENTS Total Percentage by Weight

4.0%

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France



AUG 2 0 2003

Under the Federal Insecticide, Pungicide, and Rodenticide Act, as amended, for the posticide registered under EPA Reg. No. 6845/-/

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar-

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING::	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the pr	For incidents involving HUMANS, call 1-800-680-9206 For incidents involving ANIMALS, call 1-800-548-2423 reduct container or label with you when calling a poison control center or doctor, or going for treatment.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

ŞEPA	Environmental Protection Agency Washington, DC 20460				~	Registra Amend Other		OPP Identifier Number
		Applicati	on for Pestic	ide - Se	ction	1		
1. Company/Product Numb 68451-1	er			Product Ma	3	7	3. P	roposed Classification
4. Company/Product (Name			Geor PM#	ge Larocca	3			None Restricted
Deltamethrin 4% Colla			rina.					
5. Name and Address of Ap Intervet Inc. 405 State St; P.O. B Millsboro, DE 19966	ox 318	ode)	(b)(i), to: EPA	my product	is sim		tical in co	n FIFRA Section 3(c)(3) omposition and labeling
			Section -	II				
Resubmission in res Notification - Explain Explanation: Use addition The purpose of this submiss	nal page(s) if necessar	ry. (For sectio			Applic plain b	ation. elow.	required by	/ PR Notice 2001-6,
			Section -	III	=			
1. Material This Product Wi	Il Be Packaged In:							
Child-Resistant Packaging Yes No Sertification must	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per . container	Water Soluble Yes No If "Yes" Package wgt	Packaging No. per contains		2. Type of	Metal Plastic Glass Paper	Specify)
3. Location of Net Contents		4. Size(s) Re	tail Container	-	5. Lo	cation of Lat	oel Direction	ona
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stenc	raph glued iled	Othe	er			
			Section -	V		*****		
1. Contact Point (Complete	items directly below I	for identification	n of individual to i	be contacted	, if nec	essary, to pr	ocess this	application.)
Name Mary K. Hagler			Title Regulatory Spec	cialist - Phar	maceu	ıticals	(302) 934	
	ments I have made on ny knowlinglly false or law.		all attachments th					6. Date supplications Received (Stamped)
a. Jigilatai u	.1		Pogulatory Cassi					****

5. Date

20 May 2003

Mary K. Hagler

2W-60E



(302) 934-4340

20 May 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: George Larocca
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar EPA Reg. No. 68451-1

Dear Dr. Larocca,

In accordance with PR Notice 2001-6, enclosed is an amendment of the disposal instructions for the Deltamethrin 4% Collar label (EPA Registration # 68451-1) for your review and approval.

On 14 March 2003, Intervet Inc. submitted an amendment for the First Aid statements for the Deltamethrin 4% Collar label. This amendment is still under review at EPA. The enclosed label includes the proposed First Aid statements from the amendment submitted 14 March 2003 as well as the updated disposal statements.

A completed EPA Form 8570-1 is enclosed as well as a 3 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 3 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (<u>mary.hagler@intervet.com</u>) should you have any questions.

Sincerely,

Mary K. (Hagler, MS

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

Cintervet

Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318 Tel. (302) 934-8051

FAX (302) 934-6087

PESTICIDE REGISTRATION ACTION TRACKING SYSTEM (PRAT) CODING FORM

IN PROCESSING INFORMATION

Submission Bar Code:	636181	ID Number: <u>6</u>	8457-1	Action Code: 300
PM Team: 03 Revie	wer: 10.5P	ROAT	Due Date	8 119 103
Date on Application:	5 120	/ 03		
EPA Received Date:	512	// 03		
PM Received Date:	5/2	7/03		
Chemical Code (1):		Chemical		
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Description of Action:				
Related Actions:			-	
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Response Code:	Re	sponse Date:		
75-Day Response:	Yes	No	MOS: (1)	Cite All
CRP:	Yes	No	(4)	Not Applicable
Restricted Use	Yes	No No		Selective
Exclusive Use:				
Manufacturing Use:	Yes	No		
Conditional Registration	n: Data Requi	red		
Guideline No		_	Due Date:	
Guideline No		_	Due Date	
Comments:				



(302) 934-4340

14 March 2003

Document Processing Desk (AMEND) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency Attn: George Larocca Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar EPA Reg. No. 68451-1

Dear Dr. Larocca.

In accordance with PR Notice 2001-1, enclosed is an amendment of the First Aid statements for the Deltamethrin 4% Collar label (EPA Registration # 68451-1) for your review and approval.

A completed EPA Form 8570-1 is enclosed as well as a 5 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 5 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler, MS

Regulatory Specialist - Pharmaceuticals

Intervet Inc.

Enclosure

Millsboro, DE 19966-0318 Tel. (302) 934-8051 FAX (302) 934-4292

- See read instructions on reverse before completing form

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ese read instructions o	n reverse before comple	ting form.		Form App	roved. O	MB No. 20	70-006	O. Approval	expires 2-28-
United States Environmental Protection Washington, DC 20					✓ Amend		ndment		fier Number 263
	Wash					her		Ι α τ	
		Applicati	on for Pestici	de - Sect	ion I		<u> </u>		
1. Company/Product Num 68451-1	ber		ł .	Product Mana e Larocca	ger		3. Pr	oposed Class	ification Restricted
4. Company/Product (Nam Deltamethrin 4% Coll			PM#		03			J	
5. Name and Address of A	Applicant (Include ZIP Co	ode)	6. Exp	edited Reve	eiw. In	accordanc	e with	FIFRA Secti	ion 3(c)(3)
Intervet Inc.				ny product is	similar	or identica	ıl in co	mposition a	nd labeling
405 State St; P.O. E	3ox 318		to:	Don No					
Millsboro, DE 1996	6		EPA	Reg. No					
Check if the	his is a new address		Produ	ict Name					
			Section -						
✓ Amendment - Expl	ain below.			Final printed Agency lette		repsonse to)		
Resubmission in re	sponse to Agency lette	r dated		"Me Too" A		. –			
Notification - Expla	in below.			Other - Expla	in below	•			
Explanation: Use additi	and page(a) if pages	u. (Eas annti-	and Section II)						
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The purpose of this submis	ssion is to revise the first	aid statements	s for the Deltamethin	4% collar label	as requir	ed by PR No	otice 20	01-1,	
			Section - I	11					
1. Material This Product W	Vill Be Packaged In:								
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6. Manner in Which Label i	is Affixed to Product	Litho	graph r glued ciled	Other					_
		Otom	Section - I	V				• •	
1. Contact Point (Complet	te items directly below i	for identificati			necessa	y, to proce	ss this	application.)	
Name			Title			Tel	lenhone	Ng.*(fift/fugle	Area Code)
Mary K. Hagler			Regulatory Speci	alist - Pharma	aceutical	I		-4340	
		Certific	ation		,,,,,			6. Date Appl	ication
certify that the stat	tements I have made or			ereto are true.	accurate	and come	ete:	Received	
I acknowledge that a	any knowlinglly false or							(Starr	nped)
both under applicabl	e law.						•••	•	
2. Signeture			3. Title					••••	
Man KS	Nr. 100		Regulatory Special	ist - Pharmace	uticals		•		

Mary K. Hagler

5. Date

14 Mar 2003

Please need Instructions on reverse		Posistuati	
SEPA Environmental Prote Washington, D	ection Agency	Registrati Amendm Other	TOTAL THE RESIDENCE OF THE PARTY OF THE PART
Appli	cation for Pesticide - Se	ection I	#
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4. Company/Product (Name)	Pana .		None Restricted
and Address of Applicant (Include ZIP Code) Check if this is a new address		ct is similar or identic	se with FIFRA Service 3(c)(3) al in company and labeling
	Section - II		7
Notification - Explain below. Explanation: Use additional page(s) if necessary. (For a		Explein (14	
		n	
	Section - III		
1. Material This Product Will Be	Section - III		Y N
Child-Resistant Packaging Yes* No If "Yes" No. p	Water Sand Packaging	er =	Metal Plastic Glass Paper
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5. Date

4. Typed Name

11

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and meinteining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden astimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for ell registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and eddress shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product [Amendment], for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that partains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explenation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Salf-explanatory.
- 8. EPA Use Only.

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Registra	tion
Amenda	nent
Other	r

Def Identifier Number

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. Company/Product (Name)	w		PM# "		0		Nane Restricted
e, Name and Address of Ap	oplicant (Include ZIP Co	ode) :	-	(b)(i), m to: EPA R				FIFRA Secretary 3(c)(3)
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Amendment - Explain Resubmission in resubmission - Explain	ponse to Agency lette	r dated	- s. Nga		Final printed la Agency letter o "Me Too" Appl Other - Explain	lated ication.	w 6	- T
			Section	on - I	1			
1. Material This Product W	ill Be Factoged In:		-	3				
Child-Resistant Packaging Yes* No No must	Unit Packaging Yes No If "Yes" Unit Packaging wgt	No. per	IP/	i es	No. per container	2. Type o	Metal Plastic Glass Paper Other (5	Specify)
3. Locumon of Net Contents	Information Container	4. Gizule) Ker	all Containe	ir i	E.	On Lat	el	me opanying product
6. Manner in Which Label is	Affixed to Product	Littings Paper Standi	iach glirad lad		Other _			
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1. Contact Point Complete	e items directly alow	for identification	n of individ	ual to be	e contacted, if n	ecessary, to	process this	application.)
Name	11/1		Title				Telephon	e No. (Include Area Code)
	ements I have made or my kniewingly false or a law.		all attachm					6. Date Application Received (Stamped)
2. Signature			3. Title					
4. Typed Name			5. Date				* *	13

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels mey be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only.

 Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product,
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

Lese read instructions on reverse before completing form.	Form Approved, OMB No. 2070-0060, Approvel expires 2-28-99
SEPA Environmental Protecti Weshington, DC 20	Registration OPP Identifier Number ion Agency Amendment
Applicati	on for Pesticide - Section I
1. Company/Product Number Intervet Inc./68451-1	2. EPA Product Manager George Larocca None Restricted
4. Company/Product (Name) Intervet Inc./ Deltamethrin 4% Collar	PM#
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 405 State St.; P.O. Box 318 Millsboro, DE 19966 Check if this is a new address	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name
	Section - II
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below.	Final printed labels in repsonse to Agency latter dated "Me Too" Application. Other - Explain below. MAR 2 9 2002
provisions of PR Notice 98-10 and EPA regulations at 40 CFR 15 formula of this product. I understand that it is a violation of 18 U.S	(see attached draft label for proposed changes). This notification is consistent with the 2.46, and no other changes have been made to the labeling or the confidential statement of S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this d 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to FRA.
	Section - III
Lebel Conteiner	Water Soluble Packaging Yes No If "Yes" Package wgt Solution The soluble Packaging Other A soluble Packaging A solution Other Other Other Other Other
Pape	ograph Other s or plued iciled
	Section - IV
1. Contact Point (Complete items directly below for identificat	tion of individual to be contacted, if necessary, to process this application.)
Name Mary K. Hagler	Title Regulatory Specialist - Pharmaceuticals Telephone No. (Include Area Code) (302) 934-4340
Certific I certify that the statements I have made on this form an I acknowledge that any knowlingly false or misleading s both under applicable law.	nd all attachments therato are true, accurate and complete.
2. Signeture May K. Hagle	3. Title Regulatory Specialist - Pharmaceuticals
4. Typed Name Mary K. Hagler	5. Date 21 March 2002 5IG

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Paperwork Reduction Act Notice and Instructions

<u>Paperwork Reduction Act Notice</u>: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

<u>Instructions</u>: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific Instructions: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from the party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3(c) 3(b) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar, or identical to other pesticide products that are currently registered with the EPA. In order for you application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

Section II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by . . . "; "reregistration submission"; "general label revision of use directions." Attach a separate page is additional space is needed.

Section III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packaging types and humber per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- 3. ••• Location of Net Contents Indicate the location of the net contents information for your product.
- 4. •• Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. ••• Location of the Use Directions Indicate the location of the use directions for your product.
- 6. . . Manner in which label is affixed to product Indicated the method product label is attached to retail container.

Section IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-teo," regeistration, etc.

- 1-5. Self-explanatory •
- 6. EPA Use only

NOTIFICATION MAR 2 9 2002

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

→ Kills Fleas and Ticks for up to 6 Months ←
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (including deer ticks which may carry Lyme disease)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:

Deltamethrin

Percentage by Weight

4.0%

INERT INGREDIENTS

Total

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT, 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France



READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO RUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

fage 2 of 2 21 march 2000



(302) 934-4340

21 March 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Company #: 54382). The label was previously approved per EPA letter dated 17 November 1998 and modified via notification dated 21 Dec 2001.

1. The following text, consistent with statements on page 2 of the label, is being added to page 1 of the label:

Kills Fleas and Tick for up to 6 months

2. The following statement is being added to page 1 of the label:

See Back for additional Precautionary Statements

2. The following statement is being added to page 2 of the label:

Collar also kills ticks for up to 6 months.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes of the label are underlined, highlighted and bracketed with arrows (→←). In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler, MS

Maux K.

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

Cintervet

Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318 Tel. (302) 934-8051 FAX (302) 93**4-6**292

SEPA	Environmental	nited States		V	Registrat Amendm Other		OPP Identifier Number
		Applicatio	n for Pesticide	- Section	1		
1. Company/Product Number Intervet Inc./68451-1			2. EPA Prod George L	luct Manager arocca	2	3. Pr	oposed Classification None Restricted
4. Company/Product (Name) Intervet Inc./ Deltameth			PM#				
Intervet Inc. 405 State St.; P.O. Bo Millsboro, DE 19966	ox 318	del		roduct is sir			FIFRA Section 3(c)(3) mposition and labeling
			Section - II	Tallio			
Resubmission in responsible Revision: Use addition Label Revision: Revision of provisions of PR Notice 98-1 formula of this product. I under notification is not consistent enforcement action and penals	nal page(s) if necessar marketing claim per PR 0 and EPA regulations derstand that it is a viola with the terms of PR No	ry. (For section R Notice 98-10 (at 40 CFR 152- ation of 18 U.S. otice 98-10 and	on I and Section II.) see attached draft label 46, and no other chang C. Sec. 1001 to willfully 40 CFR 152.46, this pro	es have been make any false	changes). This r	eling or the	ne confidential statement of ther understand that if this
			Section - III				
1. Material This Product Wi	Be Packaged In:						
Child-Resistant Packaging Yes No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt	No. per container	Water Soluble Pack Yes No If "Yes" Package wgt	No. per container	2. Type of 0	Metal Plastic Gless Paper	Specify)
3. Location of Net Contents	Information	4. Size(s) Re	teil Container	5.1	Location of Lab	el Directi	ons
8. Manner in Which Label is	Affixed to Product	Lithor Paper Steno	graph glued iled	Other _			•
			Section - IV				
1. Contact Point (Complete	items directly below	for identification	on of individual to be c	ontacted, if n	ecessary, to pro	cess thi	s application.)
Name Mary K. Hagler	7		Title Regulatory Speciali	st - Pharmac		Telephor (302) 93	ne No. (Include Area Code 34-4340
I certify that the state I acknowledge that a both under applicable	ny knowlinglly false or	Certifica n this form and r misleading st	ation i all attachments there atement may be punis	to are true, a	ocurate and con or imprisonment	nplete.	6. Date Application Received (Stamped)
2. Signeture	tagle		3. Title Regulatory Specialist	- Pharmaceuti	icals		
4. Typed Name	0		5. Date		1		

Mary K. Hagler

21 March 2002

\$EPA	United States Environmental Protection Agency Washington, DC 20480			2	Registra Amenda Other		OPP Identifier Number
		Applicati	on for Pesticide - Se	ction	1		
1. Company/Product Number Intervet Inc./68451-1	or .		2. EPA Product N George Larocc			3. P	roposed Classification
 Company/Product (Name Intervet Inc./ Deltamet) 			PM#				
5. Name and Address of Ap Intervet Inc. 405 State St.; P.O. B Millsboro, DE 19966	ox 318	ode)	The ball of the same of the sa	ct is sin			FIFRA Section 3(c)(3) emposition and labeling
			Section - II				
Notification - Explain Explanation: Use additio Label Revision: Revision of provisions of PR Notice 98- formula of this product. I un	nai page(s) if necessa marketing claim per PF 10 and EPA regulations derstand that it is a viol with the terms of PR N	ry. (For section R Notice 98-10 at 40 CFR 152 atton of 18 U.S otice 98-10 and	Other - B On I and Section II.) (see attached draft label for proceed, and no other changes have at 40 CFR 152.46, this product management of the company of	e been n	eation. elow. manges). This made to the la	beling or the	ne confidential statement of ther understand that if this
			Section - III	-		_	
1. Material This Product Wi	Il Se Packaged In:						
Child-Resistent Packaging Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgf	No. per	Weter Soluble Packaging Yes No If "Yes" Package wgt No. p		2. Type of	Metal Plastic Glass Paper	Specify)
3. Location of Net Contents	Information Container	4. Size(s) R	stail Container	5. L	ocation of La	bel Directi	one
8. Manner in Which Label is		Litho Pape Sten	graph 0 r glued ciled	ther			•
			Section - IV				
1. Contact Point (Complete	items directly below	for identificat	ion of individual to be contact	ed, if ne	cessary, to p	rocess thi	s application.)
The state of the s			Title Regulatory Specialist - Pharmaceuticals			Telephone No. (Include Area Code) (302) 934-4340	
	ny knowlinglly false o		ation d all attachments thereto are tatement may be punishable b				6. Date Application Received (Stamped)
2. Signature Mary K.	tagle		3. Title Regulatory Specialist - Phan	. Title Regulatory Specialist - Pharmaceuticals			
4. Typed Name Mary K. Hagler	5. Date 21 March 2002						

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

→ Kills Fleas and Ticks for up to 6 Months ← LONG LASTING PROTECTION FOR UP TO 6 MONTHS Kills Ticks (including deer ticks which may carry Lyme disease) ALSO KILLS FLEAS

ACTIVE INGREDIENT: Deltamethrin

Percentage by Weight

4.0%

INERT INGREDIENTS

96.0%

100.0%

Total

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France

Page 1 of 2 21 March 2002

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar,

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC, be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

Page 2 of 2 21 march 2382



(302) 934-4340

21 March 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Company #: 54382). The label was previously approved per EPA letter dated 17 November 1998 and modified via notification dated 21 Dec 2001.

1. The following text, consistent with statements on page 2 of the label, is being added to page 1 of the label:

Kills Fleas and Tick for up to 6 months

2. The following statement is being added to page 1 of the label:

See Back for additional Precautionary Statements

2. The following statement is being added to page 2 of the label:

Collar also kills ticks for up to 6 months.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes of the label are underlined, highlighted and bracketed with arrows (→←). In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (<u>mary.hagler@intervet.com</u>) should you have any questions.

Sincerely,

Mary K. Hagler, MS

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

intervet

Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318 Tel. (302) 934-8051 FAX (302) 934-4292

MAY-14-2002 08:47 VIRBAC CORP. 8178312878 Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved, OMB No. 2070-0044. Approval Expires 1-31-96 United States Environmental Protection Agency 285**€**47 Office of Pesticide Programs (H7505C) 401 M Street SW Washington, DC 20460 Notice of Supplemental Distribution of a Registered Pesticide Product Instructions After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown. If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency. This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor. Distributor Company Number EPA Registration Number of Product 0 68451-1 8 2382 Note: Do not submit distributor product labels Name of Registered Product (basic product name accepted by EPA) Distributor Product Name Deltamethrin 4% Collar Preventef-D Flea & Tick Collar for Dogs Name and Address of Distributor (Type: include ZIP code) Virbac AH, Inc. PO Box 162059 Fort Worth, TX 76161 Read All Conditions Before Signing The distributor product must have the same composition as the basic product. 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product. 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however that specific claims may be deleted if by doing so, no other changes to the label are necessary. 4. The product must remain in the manufacturer's unbroken container. 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number. 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for ...," distributed by..."; or sold by..." to show that the name is not that of the manufacturer. 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product. Distributor We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice. Signature and Title of Distributor michelle foxus. Registration Specialist 55/14/100

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

16 May 2002

EPA Form 8570-5 (Rev. 2-92) Previous editions are obsolete



United States Environmental Protection Agency Office of Pesticide Programs (H7505C)

401 M Street SW Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the Distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

68451-1 🛭

Distributor Company Number

4758

Note: Do not submit distributor product labels

Name of Registered Product

(basic product name accepted by EPA)

Distributor Product Name

Deltamethrin 4% Collar

Adams Delta Force Tick Collar for Dogs

Name and Address of Distributor

(Type; include ZIP code)

Pet Chemicals P.O. Box 18993 Memphis, TN 38181

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered product.
 - The labelling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- 4. The product must remain in the manufacturer's unbroken container.
- 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for..", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

Bill Washburn, Product Development & Regulatory Affairs Manager

9/28/01

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

S. Lee Whaley, Manager, Regulatory Affairs - Pharmaceuticals

EPA Form 8570-5 (Rev.2.92)

Previous editions are obsolete.

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Cover sheet

Telefax Transmittal

INTERVET INC

3029344209

P.01/07

AKZO NOBEL

Page of 7 Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966 (302) 934-8051

February 14, 2002

7...pages including cover sheet.

PERSON TO: COMPANY/DEPT TO: FAX NUMBER:

Mrs. Linda Arrington

U.S. Environmental Protection Agency

703-305-6920

PERSON FROM: COMPANY/DEPT FROM: FAX NUMBER:

S. Lee Whaley, MS

Intervet Inc.,

Fax: 302-934-4209

Manager, Regulatory Affairs – Pharmaceuticals Regulatory Affairs

Phone: 302-934-4385

RE: Deltamethrin 4% Collar – EPA Registration #68451-1 (Notification Submitted 21 Dec 2001)

Dear Mrs. Arrington:

As we discussed today, please find attached two EPA letters (both dated 14 March 2001) regarding the change of name and ownership of company numbers 68451 and 54382 from Hoechst Roussel Vet to Intervet Inc. Both company numbers now refer to:

Intervet Inc. 405 State Street, P.O. Box 318 Millsboro, DE 19966-0318.

As we discussed, Intervet Inc. is the primary registrant of Deltamethrin 4% Collar (EPA Registration #68451-1) and, as such, Item 1 of the Form 8570-1 Notification submitted 21 December 2001 should have referenced "68451-1" instead of "54382/68451-1". I apologize for any confusion this may have caused. Thank you once again for the notification acknowledgement sent on 14 January 2002. Please feel free to contact me should you have any further questions.

Sincerely,

S. Lee Whaley, MS

Manager, Regulatory Affairs - Pharmaceuticals

Intervet inc.

Intervel

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.



Page 2 of 7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 14, 2001

Mr. Bryan Gathagan
Vice President, Information &
Control
Invervet, Inc.
405 State Street, PO Box 318
Hillsboro, DE 19966-0318

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Gathagan:

Subject: Change of Name and Ownership of Company Number 68451

Pursuant to your letter and agreement of February 7, 2001, we have approved the change in name and ownership of Hoechst-Roussel Vet, company number 68451.

Our records are being amended to show the registrant and Agent under company number 68451 as follows:

Intervet, Inc. 405 State Street; FO Box 318 Millsboro, DE 19966-0318

Authorized Representative:

Bryan Gathagan (302) 934-8051

The effective date of this change is the date of this letter.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

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Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

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Page 4 of ?

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Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker

Information Management Specialist

Information Services Branch

Information Resources & Services Div. (7504C)

CC: Mr. Brett Whitehead
 Vice President of Animal Health Business Unit
 Hoechst-Roussel Vet
 Perryville Corporate Park; PO Box 4010
 Clinton, NJ 08809-4010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Page 5 of 7

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March 14, 2001

Mr. Bryan Gathagan
Vice President, Information &
Control
Invervet, Inc.
405 State Street, PO Box 318
Hillsboro, DE 19966-0318

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Gathagan:

Subject: Change of Name and Ownership of Company Number 54382

Pursuant to your letter and agreement of February 7, 2001, we have approved the change in name and ownership of Hoechst-Roussel Vet, company number 54382.

Our records are being amended to show the registrant and Agent under company number 54382 as follows:

Intervet, Inc. 405 State Street; PO Box 318 Millsboro, DE 19966-0318

Authorized Representative:

Bryan Gathagan (302) 934-8051

The effective date of this change is the date of this letter.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Page 6 of 7

3029344209

2

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You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above:

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

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Page 7.f7

3

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By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker

Information Management Specialist

S. Parla

Information Services Branch

Information Resources & Services Div. (7504C)

cc: Mr. Brett Whitehead
Vice President of Animal Health Business Unit
Hoechst-Roussel Vet
Perryville Corporate Park; PO Box 4010
Clinton, NJ 08809-4010

United States Environmental Protection Agency Washington, DC 20460				·	Amendm	gistration nendment her		
		Application	n for Pestic	de - Sectio	n I			
1. Company/Product Number			2. EPA Product Manager		r	3. Proposed Classification		
			George Larocca			$\dashv \Box$	None Restricte	
Company/Product (Name) Intervet Inc./ Deltamethrin 4% Collar			FM#					
5. Name and Address of Ap Intervet Inc. 405 State St.; P.O. B Millsboro, DE 19966	de).	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name						
200.007 700			Section -			AUC	TIEICATION	
Resubmission in resp Notification - Explain Explanation: Use addition Notification of minor changes the provisions of PR Notice s of formula of this product. I i notification is not consistent enforcement action and penal 1. Material This Product Will Child-Resistant Packaging Yes No Certification must submitted	nal page(s) if necessar s to the label front panel 98-10 and EPA regulation understand that it is a view with the terms of PR No alties under sections 12	y. (For section, per PR Notice ons at 40 CFR 1 olation of 18 U. tice 98-10 and and 14 of FIFR	98-10 (see attache 52,46 , and no othe S.C. Sec. 1001 to v 40 CFR 152.46, this	er changes have t rillfully make any l s product may be	below. roposed changes been made to the false statement to). This no labeling o EPA. I fi RA and I	or the confidential statemer urther understand that if th may be subject to	
3. Location of Net Contents Label 6. Manner in Which Label is	Container	4. Size(s) Ret		5.	Location of Labe	l Directio	ns	
		Lithogr Paper Stencil						
			Section - I					
1. Contact Point (Complete	items directly below f			e contacted, if n				
Name S. Lee Whaley			Manager, Regulatory Affairs - Pharma			Telephone No. (Include Area Code) (302) 934-4385		
I certify that the state	ments I have made on ly knowlingliy felse or law.	Certificate	tion all attachments th	erato are trus, ac	ccurate and com		6. Pare Application Received (Stamped)	
2. Signature S. Till Maley Typed Name			3. Title Manager, Regulatory Affairs - Pharmaceuticals 5. Date					

S. Lee Whaley

21 December 2001

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 17 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

ACTIVE INGREDIENT:

Percentage by Weight

Deltamethrin

4.0%

INERT INGREDIENTS

96.0%

Total

100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

page 1 of 3

Hoechst Roussel Vet SA 102 route de Noisy 93235 Romainville, France

20 May 1998

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide- release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes sp.) which may carry the Lyme disease. Collar kills and repels mosquitoes (Aedes aegypti) and prevents them from feeding. This collar should be worn continuously. Reapply a new collar every 6 months:

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle-and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of net must also be treated with appropriate pest control measures to ensure control of pests. We ting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

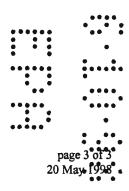
Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

The Hoechst Name and logo are registered trademarks of Hoechst AG.

© 1998 HRV S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

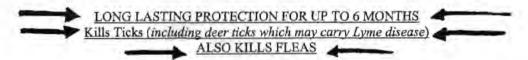


NOTIFICATION

JAN 1 4 2002

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS



ACTIVE INGREDIENT:

Deltamethrin

INERT INGREDIENTS

Total

Percentage by Weight

4.0%

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

Adjustable - One Size Fits All

-

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1 NET CONTENTS: 1 Collar NET WT. 0.9 oz

Distributed by: Intervet Inc. 405 State Street Millsboro, DE 19966

Product of France

Page 1 of 2 21 Dec 2001

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4%Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Product of France

Page 20f2 21 Dec 2001



21 December 2001

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

UAN 1 4 2002

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the Deltamethrin 4% Collar label (EPA Registration #: 68451-1; Intervet Inc., Gempany #: 54382). The label was previously approved per EPA letter dated 17 November 1998.

1. The following text, consistent with statements on page 2 of the label, are being added to page 1 of the label:

LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (including deer ticks which may carry Lyme disease)
ALSO KILLS FLEAS

2. The following statement is being added to page 1 of the label:

Adjustable - One Size Fits All

3. The statement, "See Side Panel for additional Precautionary Statements" is revised to read:

"See Insert or Side Panel for additional Precautionary Statements"

Note also that the net wt. is being revised from 1.1 oz. to 0.9 oz. to better reflect the weight of the collar.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed changes to page 1 of the label are underlined, highlighted and bracketed with arrows (→←). Note that there are no changes to page 2 of the label. In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4385) or e-mail (<u>lee.whaley@intervet.com</u>) should you have any questions.

Sincerely,

S. Lee Whaley, MS

Manager, Regulatory Affairs - Pharmaceuticals

Intervet Inc.

Enclosure

Cintervet

Intervee Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966-0318 Tel. (302) 934-8051 FAX (300) 934-4292

41





United States Environmental Protection Age

Office of Pesticide Programs (7505C)

Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

Distributor Company Number

54382

EPA Reg. No. 68451-1 8

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

Distributor Product Name

Deltamethrin 4% Collar

Deltamethrin 4% Collar

ame and Address of Distributor (Type; include ZIP code)

Hoechst Roussel Vet 30 Independence Blvd., Box 4915 Warren, NJ 07059

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- 4. The product must remain in the manufacturer's unbroken container.
- 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on Mis Notice.

Signature and Title of Distributor

Jane Kingett, Registration Specialist

Oct 1998

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Registrant Signature and Title of

Agent for Hoechst Roussel Vet S.A. John J. Lauber, Manager, Product Reg. Date 9.0ct 1998

United States

Environmental Protection Agency

Office of Pesticide Programs (7505C) Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

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This Notice of Supplemental Distribution must be submit the concurrence and signature of both the registrant and	ted by the basic registrant. The completed form must have the distributor.
EPA Registration Number of Product 4 68451-18	Distributor Company Number 3 2781
Note: Do not subm	nit distributor product labels
Name of Registered Product (basic product name accepted by EPA) DELTAMETHRIN 4% COWAR	Distributor Product Mappe HAPPY JACK NOVATION THE FLERY TICK COLLAR FOR DOGS
Name and Address of Distributor (Type; include ZIP code)	
	475 475 4258 SOUTH HILL CAROUNA 28580 ::::
Read All Conditions	Before Signing
the registered basic product. 3. The labeling for the distributor product must bear the specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbrown. 5. The label must bear the EPA registration number of the company number. 6. Distributor product labels must bear the name and addror", "distributed by"; or "sold by" to show that	same claims as the basic product, provided, however, that er changes to the label are necessary. Sken container. The basic product, followed by a hyphen and the distributor's dress of the distributor qualified by such terms as "packed at the name is not that of the manufacturer.
[2] 아이아이들은 아이들은 아이들이 게임하면서는 [2] 전 작가 하는 밤이 그런 그런 그런 아이들은 다른 계속 취임을 하는데 하다 걸어 살게 다	o distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product.
Disease	hustor

We interful to nearket our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice,

MARCH 30, 2001

Registrant

distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this agree that the Notice.

Regulatory Specialist

EPA Form \$570-5 (Rev. 8-94) Previous editions are obsolete.

Paperwork Reduction Act Notice

The annual respondent burden for the Notice of Supplemental Distribution of a Registered Pesticide Product is estimated to average 15 minutes per response, including time for reviewing the instructions, searching existing at a sources, gathering and maintaining the datameteded, and completing and reviewing the information. Send comments regarding this burden, to Chief, information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to Paperwork Reduction Project (OMB No. 2070-0044), Office of Management and Budget, Washington, DC 20503, Marked "Attention Desk Officer for EPA."

7 1786

ling and wind or Thempany Precia

NOV 17 1998

John J. Lauber Hoechst Roussel Vet Agent for Hoechst Roussel Vet S.A. 30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Subject:

Deltamethrin 4% Collar

EPA Registration No. 68451-1 Amendment dated June 4, 1998

Dear Mr. Lauber:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you:

- Make the following changes to your label:
- a. Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable. Black-legged ticks is also acceptable. However, if a species name specific claim is made, then only lxodes scapularis and/or lxodes pacificus may be used in addition to the terms above. Ixodes sp. is not acceptable, and should be removed from the label and the above species names should replace it.
- b. The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:
- 1) The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.

The data do not support the "kill" claim for mosquitoes. The range was 69% -91.1%. The 91.1% mortality result was for one data point only. All other

	1000 14 (100)			nd de la nomb	100		OFFICE	AN PILE COPY
DATE								
SURNAME								
SYMBOL	Subdivision	G Guidelin	es.					
		and the second second second	The second secon	DEIO WOMEN WREN	idalis is iess tr	nan the 95%	required by	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-2-

2. Submit two copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. I have also enclosed copies of the reviews for your records. If you have any questions about this letter, please contact Beth Edwards at (703) 305-5400.

Sincerely yours,

George T. LaRocca Product Manager 13 Insecticide Branch

Registration Division (7505C)

Beth Edwards

Enclosures

CONCURRENCES								
SYMBOL		1			3. E. T.			Farmer and
SURNAME)					***************************************		************	
DATE)				*************	************	***************************************	***************	
EPA Form	1320-1A (1/90)			Printed on Recycles	t Paner		OFFICE	ALL BILE COPY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

21 /OCTOBER/1998

MEMORANDUM

Subject:

EPA Reg. No.: 68451-00001 Deltamethrin 4% Flea Collar

DP Barcode: D248074 Case No: 034680

From:

To:

Eugenia McAndrew, Biologist

Technical Review Branch Registration Division (7505C)

_

Beth Edwards, PM Team 03

Insecticide Branch

Registration Division (7505C)

Applicant:

Hoechst Roussel Vet

30 Independence Blvd.

P.O. Box 4915 Warren, NJ 07059

FORMULATION FROM LABEL:

Active Ingredient(s):

097805 Deltamethrin

% by wt.

40

Inert Ingredient(s):

96.0

Total:

100.%

ACTION REQUESTED: "Please review information submitted to support the revision of the First Aid Statement for the subject product to delete "induce vomiting."

BACKGROUND: The Registrant has submitted a letter proposing to revise the label concerning first aid statements for EPA Reg. No. 68451-00001 Deltamethrin 4% Collar. The revision would delete the instruction to "induce vomiting." The letter states as follows:

"Since ingestion of even an entire flea collar does not appear to cause much of an acute toxicity hazard, except perhaps in very small children (and animals), it is our opinion that vomiting should not be induced as first aid treatment following collar ingestion due to the potential danger of aspiration (or other physical trauma) of the foreign material particularly if the collar has been bitten or chewed into smaller segments.

In certain circumstances, particularly with ingestions by small children (and animals) for example, it may be necessary to retrieve the collar or segments of collar from the gastrointestinal tract using medical or pharmacological methods. Procedures such as this should be left up to the physician (veterinarian)."

RECOMMENDATIONS: We have reviewed the arguments and deem it appropriate to remove the statement "induce vomiting" from the label. The new label submitted contains the correct first aid statements for acute oral exposure.

DP BARCODE: D248074

CASE: 034680

SUBMISSION: S546541

DATA PACKAGE RECORD BEAN SHEET

DATE: 08/03/98 Page 1 of 1

11-31-98

* * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

ACTION: 305 TECH-LBL REV AMND DATA RE

RANKING : 10 POINTS ()

CHEMICALS: 097805 Deltamethrin

4.0000%

ID#: 068451-00001 DELTAMETHRIN 4% COLLAR

COMPANY: 068451 HOECHST ROUSSEL VET S.A.

PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 PM TEAM REVIEWER: BETH EDWARDS 703-305-5400 ROOM: CM2 206

RECEIVED DATE: 07/09/98 DUE OUT DATE: 01/15/99

* * * DATA PACKAGE INFORMATION * * *

EXPEDITE: N DATE SENT: 08/03/98 DATE RET.: DP BARCODE: 248074

CHEMICAL: 097805 Deltamethrin

P TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT DIW : RD BRAN: TRB SECT: TOX

REVR : CONTR:

ADMIN DUE DATE: 12/31/98 meck NEGOT DATE: PROJ DATE:

* DATA REVIEW INSTRUCTIONS * * *

Please review information submitted to support the revision of the First Aid Statement for the subject product to delete "induce vomiting."

MRID No. 445787-01

Thanks, Beth Edwards 305-5400

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * *

BRANCH/SECTION DATE OUT DP BC DUE BACK INS CSF LABEL 248072 IB/PM03 08/03/98 12/31/98 Y Y Y

Counow

EFFICACY STUDY REVIEW

by Kevin J. Sweeney, Entomologist - IB

To: Beth Edwards

Date: September 15, 1998

EPA Reg. or File No.: 68451-1

Product Name: Deltamethrin 4% Collar

Registrant: Hoechst Roussel Vet

PM: George LaRocca

Action: 305

Submission No. S546541

DP#: D248072

Chemical: deltamethrin 4%

Studies Submitted:

MRID # 44578702 Review of the Anti-feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies

MRID # 44578703 Initial "Kill" Activity of Deltamethrin 4% Collars Against *Ixodes* scapularis Nymphs using Treated Dog Hair as the Testing Substance

MRID # 44578704 Report of Laboratory Trials on the efficacy of Deltamethrin 4% Dog Collars for Control of Ticks - *Ixodes ricinus* and *Rhipicephalus sanguineus* in Dogs

MRID # 44602901 Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for control of Ticks - *Ixodes ricinus* and *Rhipicephalus sanguineus*.

MRID # 44578705 Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality, and Blood feeding of Adult *Aedes aegypti* Mosquitoes.

Comments:

The registrant wishes to add deer ticks and mosquitoes to the label.

Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable, black-legged ticks I also acceptable. However, if a species name specific claim is made - then only *Ixodes scapularis* and/or *Ixodes pacificus* may be used in addition to the terms above. *Ixodes sp.* is not acceptable, should be removed and the above species names should replace it.

The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:

- 1. The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.
- 2. The data do not support the "kill" claim for mosquitoes. The range was 69% 91.1%. The 91.1% mortality result was for one data point only. All other measurements of mortality were below 90%. This is less than the 95% required by Subdivision G Guidelines.

I do not think we should entertain "aids in" claims for any repellent product or one meant to kill any public health pest feeding on a host.

DP BARCODE: D248072

CASE: 034680

DATA PACKAGE RECORD

SUBMISSION: S546541

BEAN SHEET

DATE: 08/03/98

Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

ACTION: 305 TECH-LBL REV AMND DATA RE

RANKING : 10 POINTS ()

CHEMICALS: 097805 Deltamethrin

4.00008

ID#: 068451-00001 DELTAMETHRIN 4% COLLAR

COMPANY: 068451 HOECHST ROUSSEL VET S.A.

PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 217 PM TEAM REVIEWER: BETH EDWARDS 703-305-5400 ROOM: CM2 206

RECEIVED DATE: 07/09/98 DUE OUT DATE: 01/15/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 248072 EXPEDITE: N DATE SENT: 08/03/98 DATE RET.: /

CHEMICAL: 097805 Deltamethrin

P TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 12/31/98 NEGOT DATE: DIV : RD PROJ DATE: BREN: IB

SMITT PM03 REVR :

CONTR:

* DATA REVIEW INSTRUCTIONS * * *

attn: Efficacy

Please review studies submitted to support claims for deer ticks and mosquitoes.

MRID Nos. 445787-02; -03; -04; -05; and 446029-01.

Thanks. Beth

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

HOECHST ROUSSEL VET S.A. 30 INDEPENDENCE BLVD. P.O. BOX 4915 WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mai JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Colar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently
 registered label are shown with a line drawn through them, while the words added to
 the label are shown as underlined text.
- · Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4%-Collar First Aid Statement (EPA Guideline No. N/A). (MRID.No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3).

(MRID No.44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphis using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3). (MRID No.44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars of Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in the Dogs (EPA Guideline No.91-3).

(MRID No. 24602901

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult Aedes aegypti Mosquitoes (EPA Guideline No.____).

(MRID No.4457870__)

 Company Official: John J. Lauber, Ph.D. Name

e ()

Signature

6. Company Name:

Hoechst Roussel Vet

P. O. Box 4915

Warren, N.J. 07059

7. Company Contact:

John J. (Jack) Lauber, Ph.D.

Phone: 908/231-3426 FAX: 908/231-4462 Teresa,

7/10

The pages in German (25-182) were raw data. The registrant said this was not really necessary for review and so I have taken them out. They faxed me a replacement for page I to say "page I of 24" instead of "... 182".

Please Send to SIG for mRID. Thanks, Bethe.

Administrative

Materials

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

HOECHST ROUSSEL VET S.A. 30 INDEPENDENCE BLVD. P.O. BOX 4915 WARREN, NJ 07059

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/10/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [05]:

* An English translation is required for all work originally reported in other languages.

Pgs. 25-132

SIG See me if you have any questions about this resulmission

7/15

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the **following** in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently
 registered label are shown with a line drawn through them, while the words added to
 the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

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Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.Reject (05)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).

(MRID No.44578705)

Company Name:

6.

5. Company Official: John J. Lauber, Ph.D.

Name

Hoechst Roussel Vet

P. O. Box 4915

Warren, N.J. 07059

7. Company Contact: John J. (Jack) Lauber, Ph.D.

Phone: 908/231-3426 FAX: 908/231-4462 - 1st code in/out 7800 305-BE PR FET JUN 18 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

HOECHST ROUSSEL VET S.A. 30 INDEPENDENCE BLVD. P.O. BOX 4915 WARREN, NJ 07059

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Rejected study [05]:

* An English translation is required for all work originally reported in other languages.

P35. 25-/82.

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In beef, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently
 registered label are shown with a line drawn through them, while the words added to
 the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the processed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

Volume 1: John J. Lauber (1998), Revision of Deltamethrin 4% Collar First Aid Statement (EPA Guideline No. N/A). (MRID No. 44578701)

Volume 2: R. Killick-Kendrick (1997), Review of the Anti-Feeding Effects of Synthetic Pyrethroids to Mosquitoes and Phlebotomine Sandflies (EPA Guideline No.91-3). (MRID No.44578702)

Volume 3: R. L. Slone (1998), Initial "Kill" Activity of Deltamethrin 4% Collars Against Ixodes scapularis Nymphis using Treated Dog Hair as the Testing Substrate (EPA Guideline No.91-3). (MRID No.44578703)

Volume 4: A. Liebisch and U. Reimann (1997), Report of Laboratory Trials on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

(MRID No.Reject (05)

Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).

(MRID No.44578705)

5. Company Official: John J. Lauber, Ph.D. Name Signature

6. <u>Company Name:</u> Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

7. Company Contact: John J. (Jack) Lauber, Ph.D. Phone: 908/231-3426

FAX: 908/231-4462

445787-00

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail JLauber@HRVet.com

June 4, 1998

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar, EPA Reg. No. 68451-1

Amended Registration Application

Dear Mr. LaRocca:

As the agent of Hoechst Roussel Vet S.A., we are making this submission of an amended registration application concerning Deltamethrin 4% Collar. In brief, we are proposing to revise the label concerning the First Aid Statement (deletion of "inducing vomiting"), as well as adding claims for deer ticks and mosquitoes.

I am enclosing the following in support of this amended registration of Deltamethrin 4% Collar:

- Amended Registration Application
- 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text.
- Transmittal Document detailing the reports justifying the proposed label changes

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Enclosures

98 05 20d

TRANSMITTAL DOCUMENT

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Hoechst Roussel Vet P. O. Box 4915 Warren, N.J. 07059

2. Regulatory action in support of which this package is submitted:

Amended registration of Deltamethrin 4% Collar

3. Transmittal date:

June 1, 1998

4. List of submitted studies:

Cover Letter

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(MRID No.44578704)

Volume 5: A. Liebisch and U. Reimann (1997), Report of a Controlled Field Trial on the Efficacy of Deltamethrin 4% Dog Collars for Control of Ticks (Ixodes ricinus and Rhipicephalus sanguineus) in Dogs (EPA Guideline No.91-3).

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Volume 6: R.L. Stone (1998), Determine the Effect of Deltamethrin 4% Collars on Repellency, Mortality and Blood Feeding of Adult *Aedes aegypti* Mosquitoes (EPA Guideline No.____).

(MRID No.4457870=)

5. Company Official: John J. Lauber, Ph.D.

Name

6. Company Name:

Hoechst Roussel Vet

P. O. Box 4915

Warren, N.J. 07059

7. Company Contact:

John J. (Jack) Lauber, Ph.D.

Phone: 908/231-3426 FAX: 908/231-4462

(A) SEF	United States Environmental Confice of Pestic Washir Applicat		505C) X	Registra Amenda Other	The second secon
		Section I			
1. Company/Product Num	ber COAFT 1		. EPA Product Manager	03	3. Proposed Classification
68451-2 4. Company/Product (Name)			G. LaRocca/13	03	None Restricte
	The section will be a section	~	13 03		
	tamethrin 4% Colla: Applicant (Include ZIP Code)			la accorda	nce with FIFRA Section 3(c)(3
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vvalien, ie.o.	0,000	Section I I	TOGGCT Wallie		
		Section 11	Finel adated labels	in menonen i	
Amendment - Explain	below		Final printed labels Agency letter date	d	
Resubmission in resp	onse to Agency letter dated		"Me Too" Application	on.	
Notification - Explain t	pelow.				12
			Other - explain bek	UW.	
	tatement - deleting for Use - addition	of claims f		and mosqui	toes 445787
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2. Directions 1. Material This Product Child-Resistant Packaging Yes* No	Will Be Packaged in: Unit Packaging Yes No If "Yes," Unit Package wgt. contr	Section III Water So Yes No Per If "Yes,"	luble Packaging No. per wgt. container	2. Type of C	Container Metal Plastic Glass Paper Other (Specify)
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B

United States Environmental Protection Washington, DC 204					Registration Amendmen Other			
		Applicati	on for Pesticide - S	ection	Te .			
1. Company/Product Nu	imber	2. EPA Product	Manager		3. Pr	oposed Classification		
4. Company/Product (N	ame)	PM#	PM#			None Restricted		
	f Applicant (Include ZIP Co	odel	The second secon	uct is sir	milar or ident		FIFRA Section 3(c)(3) imposition and labeling	
			Section - II					
Notification - Ex	response to Agency letter plain below. ditional page(s) if necessar		Other -	Explain b				
		7 ~	Section - III					
1. Material This Product Child-Resistant Packagi Yes* No Certification mus	Unit Packaging Yes No	No. per	Water Soluble Packaging Yes No If "Yes" No. Package wgt cont		2. Type of	Metal Plastic Glass Paper	Specify)	
submitted 3. Location of Net Cont			etail Container	ă.	ocation of Lab	el Directio		
6. Manner in Which Lab	el is Affixed to Product	Litho	graph r glued siled	Other	- 1			
		Stant	Section - IV					
1. Contact Point / Comp	olete items directly below i	for identificati	on of individual to be contac	ted, if ne	cessary, to pro	ocess this	application.)	
Varne			Title			Telephon	e No. (Include Area Code)	
	at any knowingly false or r		I ation d all attachments thereto are tement may be punishable b				6. Date Application Received (Stamped)	
2. Signature			3. Title					

5. Date

4. Typed Name

254630

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send-comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1: Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)]:
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable,

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

Please read instructions	on reverse before completing	form.	Form A	pproved. ON	MB No. 2070-006	0. Approval expires 05-31-98
United States Environmental Protection A Washington, DC 20460			gency	A	egistration mendment ther	254630
	A Ap	plication fo	r Pesticide - S	ection I		
1. Company/Product Num	nber		2. EPA Product N	Manager	3.	Proposed Classification
4. Company/Product (Na	me)	1	PM#	23		None Restricted
	Applicant (Include ZIP Code) this is a new address	- W - 3	(b)(i), my produ to: EPA Reg. No Product Nam	oct is similar		th FIFRA Section 3(c)(3) composition and labeling
		S	ection - II			
Amendment - Exp	esponse to Agency letter dat	ed	Agency "Me To	inted labels in letter dated o" Application Explain below		
1. Material This Product	Will Be Packaged In:	Se	ection - III			
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			ection - IV	A 11 33 31	0.500000	
	ete items directly below for it		edividual to be contact	ed, if necess.		
Name		Title			Telepho	one No. (Include Area Coda)
	atements I have made on this any knowingly false or misle					6. Date Application Received (Stamped)
2. Signature	-	3. Title				
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 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 8. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

® SEP	A A	tates Environmental of Pesticide Progra Washington, DC Oplication for	ms (H7505C) 20460 Pesticide:	X	Registra Amenda Other	mon l	OPP Identifier Number 25963 166132
		Secti	2. EPA Product	Managar		12 Om	posed Classification
Company/Product Numb	68451-1		G. LaRocc	0.00000.700	-03	3. Pro	sposed Classification
4. Company/Product (Nam			PM#	4/19			None Restricted
Dell	tamethrin 4%	Callan	-13-	0	3)	
5. Name and Address of A			6. Expedited	Review	. In accordan	ce with f	FIFRA Section 3(c)(3)
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Amendment - Explain	below		Agency k		in response to		· ·
Resubmission in respo	onse to Agency lette	r dated		Apolicatio			
Notification - Explain b	elow.						
			Other - ex	plain belo	w.		
2. Directions f	or Use - add		ms for deer t	icks a	nd mosqui	toes	
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. Material This Product V	VIII Se Packaged In	Section I	ater Soluble Packaging		2. Type of Co		**
Child-Resistant Packaging Yes* No Certification must be	VIII Se Packaged In Unit Packaging Yes	Section I	ater Soluble Packaging Yes No Yes," N		2. Type of Co	ontainer Netal Nastic	ncity)
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	rin 4% Collar			lance with FIFRA Section 3(c)(3
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 17, 1997

Mr. John Lauber Hoechst Roussel Vet Agent for Hoechst Roussel Vet S.A. 30 Independence Blvd. Warren, N.J. 07059

Dear Mr. Lauber:

Subject:

Amendment - Efficacy Claims, Compliance with PRN 96-6

Deltamethrin 4% Dog Collar

EPA Reg. No. 68451-1

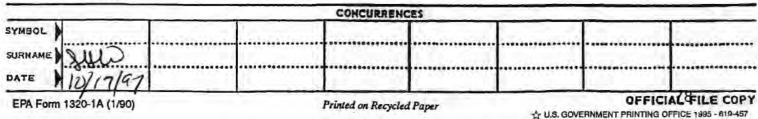
Your June 16, 1997 Submission

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosure



DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

97 JIN 19 DA:00

ACTIVE INGREDIENT:

Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]

INERT INGREDIENTS

Tota1

Percentage by Weight

4.0%

96.0% 100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

ACCEPTED

OCT 1 7 1997

Under the Federal Insecticide.
Fungicide, and Rodenticide Ast.
as amended, for the pesticide
registered under
EDE Res. No. 1645/-/

Hoechst Roussel Vet SA 102 route de Noisy 93235 Romainville, France

page 1 of 3 13 June 1997

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2 –3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus) and American dog tick (Dermacentor variabilis). This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar . Deltamethrin 4% Collar may be used in addition to a lead or constraint collar . Use only one Deltamethrin collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

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Part No. XXXXX

Universal Product Code Number (Bar Code)

page 3 of 3 13 June 1997 97 06 13a

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4. Company/Product (Name)			-	
Deltamethrin 4% Coll		13		
5. Name and Address of Applicant (Include ZIP Code) Hoechst Roussel Vet Agent for Hoechst Roussel Vet S.A 30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059				ce with FIFRA Section 3(c)(3) all in composition and labeling
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Resubmission in response to Agency letter dated_		"Me Too" Applicat	ion.	
Notification - Explain below.		Other - explain be		
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John J. Lauber Ph.D.	Title Manag	er, Product Regi	and the second second	ephone No. (Include Area Code) 908-231-3426
I certify that the statements I have made on this form a lacknowledge that any knowingly false or misleading both under applicable law.	fication and all attachmen statement may	nts thereto are true, accura be punishable by fine or in	te and complete. nprisonment or	6. Date Application Received (Stamped)
2. Signature	3. Title Mana	ger, Product Reg	istration	
John J. Lauber	5. Date	16, 1999		

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(A) SEP	United States Er Office of Pe Was Applic	nvironmental Protesticide Programs hington, DC 2046 ation for Pe	ection Agency (H7506C) 30	Registro X Amenda Other	ation	Approval expires 11-30-9: OPP Identifier Number 25-4-33-4 166132
		Section				
1. Company/Product Numb			2. EPA Product	Manager	3. Pt	oposed Classification
	68451		G. LaRocc	a/13	\neg	—
Company/Product (Nam Deli	e) tamethrin 4% Coll	ar	PM# 13			None Restricted
5. Name and Address of A Hoechst Rous	opicent (Include ZIP Code) sel Vet echst Roussel Vet S./ nce Blvd. 5	1		uct is similar or ident		FIFRA Section 3(c)(3) mposition and labeling
		Section I I				
X Amendment - Explain II Resubmission in respo	nse to Agency letter dated		Agency le	ed labels in response to the deted	•	*
statement.	oposed are the re	Section III				
Child-Resistant Packaging	Unit Packaging	I Water	Soluble Packaging	2. Type of C	container	
Yes* No * Catification must be	Yes No	lD,	/es No		Metal Plastic Glass Paper Other (Sp	ecify)
3. Location of Net Contents	Information 4. Siz	ze(s) of Retail Co	ntainer -	5. Location of Lab	,	panying product
6. Manner In Which Label Is		Lithograph Paper glued Stenciled		ther (y according)
1. Contact Point (Complete	items directly below for idea	Section IV	dual to be contact	ed, if necessary, to pro	cess this	application.)
Name	Lauber Ph.D.	Title		The same of the latest and the same of the	elephone	No. (Include Area Code) 31-3426
	s I have made on this form rowingly false or misleading				ө.	S. Date Application Received (Stamped)
2. Signature	Cauler	3. Title Manag	ger, Produc	t Registration		
. Typed Name John J.	Lauber	5. Date June	16, 199			
A Com 6570-1 /Pm 12-0	(i) Previous editions of		White - F	PA File Cooy (origina		Vellow - Andicant copy

	United States ental Protection A Washington, DC 20460			Registrati Amendm Other	lon	OPP Identifier Number
	Application fo	or Pasticide - S	Section	1		
1. Company/Product Number		2. EPA Product	Manager		3. Pro	posed Classification
4. Company/Product (Name)		PM#	1	None Restricte		
5. Name and Address of Applicant (Include a	. (to: EPA Res. N Product Nar	o			FIFRA Section 3(c)(3) mposition and labeling
Amendment - Explain below. Resubmission in response to Agency Notification - Explain below. Explanation: Use additional page(s) if necessions.	letter dated	Agence "Me T	orimed labe sy letter de oo" Applie - Explain b	Minn	to	
	-	ection - III	_			
1. Material This Product Will Be Packaged In		ater Soluble Fackagin		2 Town of Co		
Child-Resistant Packaging Yes* No If "Yes" Unit Packaging Yes No If "Yes" Unit Packaging	No. per	Yes No.	per tainer	A	Metal Plastic Glass Paper Other (S	pecify)
3. Location of Nat Contents Information Label Container	4. Size(s) Ratuil Co		5. 6	On Labeling	L Payment	ne panying product
6. Manner in Which Label is Affixed to Produ	Lithopraph Paper plued Stansiled		Other			
		ection - IV				
1. Contact Point (Complete items directly be	elow for identification of l	ndividual to be	if ne	cessary, to proc	ess this	application.)
Name	Title			> ¹	elephone	No. (Include Area Code)
I certify that the statements I have ma I acknowledge that any knowingly fals both under applicable law.						6. Date Application Received (Stamped)
2. Signature	3. Tit	•				
4 Typed Name	5 De		_		-	8

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing date sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Weshington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152,81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 8. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission of a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, registrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been assigned to you as a
 basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are ecting in behalf of another party, you must submit authorization from that perty to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application, to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

Please read instructions on r	everse before completing fo	orm.	Form App	roved. OMB No. 207	0-0060. Approval exp	res 05-31-98
⊕EPA	United Environmental Pro Washington,	tection Ag		Registrati Amendme		
	App	lication for	Pesticide - Sec	tion I		100
1. Company/Product Number			2. EPA Product Man	nager	3. Proposed Classifi	
4. Company/Product (Name)			PM#		None	Restricted
5. Name and Address of App	is a new address				e with FIFRA Section and in composition and	
The state of the s	1	Se	ction - H		170	
Amendment - Explain Resubmission in resp Notification - Explain	onse to Agency letter dated		Agancy let	d labels in response to ter dated Application.	9 50	K 050
Material This Product Will Child-Resistant Packaging Yes* No. 1	Be Packaged In: Unit Packaging Yes		er Soluble Packaging Yes	1	entainer Metal Plastic	
ertification must submitted		per If "Y	es" No. per containe		Glass Paper Other (Specify)	
3. Location of Net Contents I	nformation 4. Si	ze(s) Retail Cont	tainer	5. Location of Label On Label On Labeling	Directions secompanying produc	ct
6. Manner in Which Label is	Affixed to Product	Lithograph Paper glued Stenciled	Othe			
			ction IV			
1: Contact Point (Complete	items directly below for ide	ntification of ind	lividual to be contacted,	if necessary, to proc	ess this application.)	
Name		Title			elephone No. (Include /	Area Code)
	nents I have made on this f y knowingly false or mislead					
2. Signature		3. Title		an a		
4. Typed Name		5. Date	79		07	

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- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only.
 Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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- 1-5, Self-explanatory.
- 6. EPA Use Only.

Hoechst Roussel Vet

30 Independence Blvd. P.O. Box 4915 Warren, N.J. 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber@bed1po1.hcc.com

June 16, 1997

Data Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Att.: Mr. George T. LaRocca (PM-13)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Collar

EPA Reg. No. 68451-1

Dear Mr. LaRocca:

Deltamethrin 4% Collar was registered by the Agency in 1996 for use on dogs for control of fleas and ticks. The purpose of this submission is to revise the Deltamethrin 4 % Collar label as required by PR Notice 96-6, as well as to modify the Directions for Use and associated claims. Other label changes being proposed are the revision of the company name and insertion of a Disclaimer statement.

By way of background, Roussel Uclaf Corporation (now AgrEvo Environmental Health (EPA Company No. 432) submitted an application to the U.S. EPA to register Deltamethrin 4% Collar, a product containing 4% deltamethrin. The pending registration was transferred to Roussel Uclaf, S.A., Division Santé Animale (EPA Company No. 68451) on March 23, 1995 On June 5, 1996, the U.S. EPA registered Deltamethrin 4% Collar, to Roussel Uclaf, S.A., Division Santé Animale. Subsequently, the company name of Roussel Uclaf, S.A., Division Santé Animale was changed to Hoechst Roussel Vet S.A.

At the time the Deltamethrin 4% Collar was registered, Hoechst-Roussel Agri-Vet Company (EPA Company No. 54382) was the agent of Roussel

Uclaf, S.A. The name of Hoechst-Roussel Agri-Vet Company was changed to Hoechst Roussel Vet. In regard to this amended registration of Deltamethrin 4% Collar, Hoechst Roussel Vet is acting as the agent of Hoechst Roussel Vet S.A.

Attached you will find 5 copies of the revised label, in which the words to be deleted from the currently registered label are shown with a line drawn through them, while the words added to the label are shown as underlined text. In addition to this label showing the revisions, 5 copies of the label without crossed-out and underlined text are being submitted at this time.

Thank you in advance for processing this amended registration application and revised label. If you have any questions, please do not hesitate to contact me at the above telephone number.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Attachments

- 1. Amended Registration Application
- 2. Revised label showing deleted and new text
- 3. Revised label

CC

- A. Ahlman w/ attachments
- A. Benitz w/ attachments
- R. Dodemaide w/ attachments
- R. Muser w/ attachments

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

- **✓** GUARANTEED WATERPROOF
- ✓ KILLS FLEAS FOR 11 MONTHS
- **✓KILLS TICKS FOR 7 MONTHS**
- *←***ODORLESS**
- **FITS DOGS WITH NECKS UP TO 21"**
- **←** GUARANTEED OR YOUR MONEY BACK
- ✓— WETTING WILL NOT IMPAIR THE COLLAR'S EFFECTIVENESS
- **✓MAY BE WORN WITH REGULAR COLLAR**
- **←PATENTED INSECTICIDE RELEASE TECHNOLOGY**

ACTIVE INGREDIENT:

Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]

INERT INGREDIENTS

Total

Percentage by Weight

4.0%

96.0% 100.0%

7

=

CAUTION: Do Not Let Children Play With This Collar 5

P4:02

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

Hoechst Roussel Vet SA Roussel Uclaf, S.A. Division Santé Animale 102 route de Noisy 93235 Romainville, France

page 1 of 3 12 June 1997

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11-Month Flea Killer GUARANTEED 7-Month Tick Killer

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks. 11-month flea-killing power (and 7-month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use this product on eats. Do not use on puppies less_than 3 months of age under 12 weeks. This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterianarian immediately.

FIRST AID STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL: 1-800-228-5635, ext. 132 FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals.

Applying other pesticides on the dog may not be are not necessary and therefore should not be used on dogs while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, that one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide-release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, Maximum effectiveness may not occur for 2—3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus) and American dog tick (Dermacentor variabilis). Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, This collar should be worn continuously. Reapply a new collar every 6 months.

page 2 of 3 12 June 1997 Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle elose to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Deltamethrin 4% Collar may be used in addition to regular collar a lead or constraint collar. Use only one Deltamethrin 4% flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A.MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VETS.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

ONE SIZE FITS ALL TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

The Hoechst Name and logo are registered trademarks of Hoechst AG.

© 1997 HRV S.A.

Part No. XXXXX

Universal Product Code Number (Bar Code)

Dr. John J. Lauber Hoechst Roussel Vet Route 202-206 Bedm. P.O. Box 2500 Somerville, NJ 08876-1258

MAR 17 1997

Dear Dr. Lauber

Subject: Condition of Registration- efficacy data

Deltamethrin 3% Collar

EPA Registration Number 68451-1

Deltamethrin 4% Collar

EPA Registration Number 68451-2

Your submission dated August 19, 1996

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the following reasons given below:

1. The data summaries (MRID 44190101) submitted to the Agency are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purpose of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with the lack of sufficient detail as to the manner in which the testing was conducted, as required by 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284.

A copy of the reviews are enclosed.

Sincerely,

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosures

EFFICACY REVIEW

DATE: IN 1-13-97 OUT 3- 6-97

FILE OR REG. NO68451-1
PETITION OR EXP. PERMIT NO
DATE DIV. RECEIVED December 26, 1996
DATE OF SUBMISSION December 19, 1996
DATE SUBMISSION ACCEPTED
TYPE PRODUCT(S): (I,)D, H, F, N, R, S
DATA ACCESSION NO(S). 441901-01;D232552;S516908;Case#034680;AC:571
PRODUCT MGR. NO. 13-LaRocca/DeLuise
PRODUCT NAME(S) Deltamethrin 4% Collar
COMPANY NAME Hoechst Roussel Agri-Vet Company
SUBMISSION PURPOSE Provide performance data summaries in support of
claims for control of fleas and ticks on dogs to
establish new use for active chemical ingredient.
CHEMICAL & FORMILATION (g)- α -cyano-3-phenoxybenzyl-(1R 3R)-3-(2 2-

CHEMICAL & FORMULATION (s) -α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate 4.00% (impregnated material of unspecified bulk)

CONCLUSIONS & RECOMMENDATIONS The data summaries presented in EPA Accession (MRID) Number 441901-01, having been obtained from standard kennel tests presumably conducted according to a protocol that meets the requirements of § 95-30(b)(11)1. through 10. on pp. 280-4 and the standard of § 95-9(b)(2)(i) on p. 264 of the Product Performance Guidelines, are adequate to demonstrate the ability of the active ingredient deltamethrin to kill fleas and ticks on dogs in a preliminary manner when formulated as a collar. However, these data are incomplete for the purposes of supporting specific claims of duration of satisfactory control of fleas and ticks because of the lack of raw data for testing conducted in Arkansas, California and Oklahoma, along with lack of sufficient detail as to the manner in which testing was conducted, as required by § 95-30(b)1., 3. and 4., 6., 7., 8., 9. and 10., especially 4., 6.1, 6.4, 6.5, 6.7, 7.2, 7.3, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5, 9.7, 10.1, 10.2 and 10.4 as elaborated in paragraphs on p. 284. While Reference 1 comes closer to meeting these requirements, References 2 and 3 are only summary and abstract, respectively. References 4 through 6 are for kennel tests conducted in Europe, and while Reference 4 (to be continued)

actually gives more details as to these requirements than do the latter two reports from the U. S., it fails to identify all the formulations in the test as to active ingredient as required by § 95-30(b)2.5; References 5 and 6 are nothing more than conclusions and lack sufficient detail in many of the categories previously mentioned above. Furthermore, since the submission was not accompanied by either labeling or CSF, it is not possible to relate the conclusions and results of any of these references to the support of specific claims of duration of satisfactory control or range of flea and tick species against which the collar is found effective. Mention is made at the end of Reference 1 of original data found in the Appendix, pp. A41-A124, and of quality assurance unit inspections and the final report following the Appendix as pp. QUA1-QUA9. The submission of this information along with specific information meeting above requirements with respect to References 2 through 6 is necessary for proper review of the effectiveness of the collar, along with labeling as to the claims which these data are believed to satisfactorily support.

OBJ Vern L. McFarland, IRB

Hoechst Roussel Vet

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

441901-00

August 19, 1996

Mr. George T. LaRocca
Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

Subject:

Deltamethrin 3 and 4% Collars

EPA Registration Nos. 68451-1 and 2

Notice of Registration Dated June 5, 1996

As a condition of the registrations of the Deltamethrin 3 and 4% Collars, we committed to submit to the Agency within three months of the date of the Registration Notice, a summary of efficacy data demonstrating control of fleas and ticks. Attached you will find three copies of the report: "Deltamethrin Dog Collars - Efficacy Studies". In this report, the results of several efficacy studies with the 3 and 4% collars are presented.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Agent for Roussel Uclaf, S.A., Division Santé Animale

Attachment: 3 copies of the report "Deltamethrin Dog Collars - Efficacy Studies".

Hoechst Roussel Vet

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

December 19, 1996

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Dear Sir/Madam:

Subject:

Deltamethrin 3 and 4% Collars

EPA Registration Nos. 68451-1 and 2

Hoechst Roussel Vet submission dated August 19, 1996 EPA Report of Analysis for Compliance with 86-5 dated

September 4, 1996

On December 17, I received the "Report of Analysis for Compliance with PR Notice 86-5" (copy enclosed). The notice was dated September 4, 1996. I don't know why the notice was delayed in reaching me.

The notice indicated that our statement of no data confidentiality claims is contradicted by the markings on the first page of Reference 4. I have corrected this and am enclosing 3 copies of this corrected page. Please remove the old page from the copies previously submitted and substitute the new page.

Thank you in advance for your help.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Enclosures 961218b

1665506323

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY

EPA Reg. Office of Pesticide Programs

Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

x Registration Reregistration

(under PIFRA, as amended)

Number:

Date of Iscuance:

68451-1

K JUN 1996

Term of Issuance:

Unconditional

Name of Pesticide Product:

Deltamethrin 4% Collar

Name and Address of Registrant (include ZIP Code):

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm. 1

PO Box 2500

Somerville, NJ 08876-1258

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3) (c) (2) (B).

- Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 68451-1".
- 2. We note that in your May 14, 1996 letter you agreed to submit efficacy data supporting label claims within 3 months of the date of this notice.
- 3. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

George T. LaRocca Product Manager (13) Insecticide-Rodenticide Branch Registration Division (H7505C)

			CONCURREN	CES				
SYMBOL	signature of Approving	orrion.		17	Paleot			
SURNAME	Helen		*******	***************************************		***************************************	*********	******
DATE	A Form 8570-6	***************************************		***************************************		***********		
EPA Form	1320-1A (1/00)		Delegation D	45.00		OFFI	CIAL PILE	COPY

Printed on Recycled Paper

U.S. ENVIRONMENTAL PROTECTION AGENCY	BPA Reg.	
Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460	Number:	Date of Issuance:
NOTICE OF PESTICIDE:	1 / 1	
NOTICE OF PESTICIDE:	68451-1	
Reregistration		
(under FIFRA, as amended)	Uncondit	
	Name of Pesti	cide Product:
	Deltamet	
	Collar /	7111 40
Name and Address of Registrant (include ZIP Code):		
Hoechst-Roussel Agri-Vet Company	/	
Route 202-206 Bedm. 1		
PO Box 2500		
Somerville, NJ 08876-1258		
Note: Changes in labeling differing in substance from that accepte to submitted to and accepted by the Registration Division prior to correspondence on this product always refer to the above EPA regis	d in commection with t use of the label in c tration number.	his registration must ownerce. In any
On the basis of information furnished by the registrant, the above registered/reregistered under the Federal Insecticide, Fungicide a	named pesticide is he nd Rodenticide Act.	reby
Registration is in no way to be construed as an endorsement or rec In order to protect health and the environment, the Administrator, cancel the registration of a pesticide in accordance with the Act. with the registration of a product under this Act is not to be con exclusive use of the name or to its use if it has been covered by	on his motion, may at	any time suspend or
This product is unconditionally reg FIFRA sec. 3(c)(5). Once a pesticide is is not regarded as permanently acceptable eliminate the need for continual reasses the Agency determines that, at any time, required to maintain in effect an existing Agency will require submission of such of (3)(c)(2)(B).	registered, e. Registrat sment of pest additional d ng registrati lata under FIF	however, it ion does not icides. If ata are on, the RA section
1. Make the following label change Registration Number to read, "EPA Reg. N	Revise the 68451-1".	EPA
2. Submit two copies of the refor the record. If these conditions are registration will be subject to cancella FIFRA sec. 6(e). Your release for shipm constitutes acceptance of these conditionabel is enclosed for your records.	not complied tion in accor ent of the pr	with, the dance with oduct
George A. LaRocca		
Produgt Manager (13)		
Insegricide-Rodenticide Branch		1
Registration Division (H7505C)		1

EPA Form 8570-6

Signature of Approving Official:

Kelent

Date:

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

- **GUARANTEED WATERPROOF**
- **KILLS FLEAS FOR 11 MONTHS**
- **KILLS TICKS FOR 7 MONTHS**
- **ODORLESS**
- FITS DOGS WITH NECKS UP TO 21"
- **GUARANTEED OR YOUR MONEY BACK**
- WETTING WILL NOT IMPAIR THE COLLAR'S **EFFECTIVENESS**
- MAY BE WORN WITH REGULAR COLLAR
- PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENT:

Deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate]

INERT INGREDIENTS

Total

Percentage by Weight

4.0%

96.0%

100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1 EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 1.1 oz

ACCEPTED with COMMENTS in EPA Letter Dated

Roussel Uclaf, S.A. Division Santé Animale 102 route de Noisy

L JUN 1996

93235 Romainville, France Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8451-

May 14, 1996

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11-Month Flea Killer GUARANTEED 7-Month Tick Killer

Deltamethrin 4% Collar provides full season, 11-month flea-killing power (and 7-month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. **Do not use this product on cats.** Do not use on puppies less than 3 months of age.

This product is not recommended for use on debilitated, aged, pregnant, medicated, or nursing animals. Consult a veterinarian before using.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2 - 3 weeks after collar placement. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dog's environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus) and American dog tick (Dermacentor variabilis). Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL - TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

May 14, 1996

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258

Telephone (908) 231-3426 Fax (908) 231-4462 E-mail Lauber1@bed1po1.hcc.com

May 14, 1996

Mr. George T. LaRocca
Office of Pesticide Programs
Document Processing Desk (APPL)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

dog collar

Dear Mr. LaRocca:

Subject:

Registration Application **Deltamethrin 4% Collar**EPA File Symbol 68451-R

Your Letter Dated May 2, 1996

You indicated in your letter that the subject product is acceptable for registration provided that we agree in writing to the following:

1. Submit a summary of efficacy data demonstrating control of fleas and ticks that are consistent with labeling claims. This information to be submitted to the Agency within 3 months of the date of the registration notice

2. Make labeling changes

We agree to supply to the Agency a summary of efficacy data demonstration. control of fleas and ticks within 3 months of the date on the Notice of Registration.

I am enclosing three copies of final printed labeling in which I have incorporated all the changes that you requested.

I believe all is in order and that the Notice of Registration can be issued. Thank you in advance for receipt of the Notice.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Biologics & Pesticide Product Registration Agent for Roussel Uclaf, S.A., Division Santé Animale

Enclosure

cc by e-mail

- L. Ahlman
- A. Benitz
- C. Chieze
- R. Dodemaide
- A. Donoghue
- C. Focheux
- D. Frey

PY Kravtchenko

R. Muser

JP Scheid

96 05 08b

166 5494967

0 2 MAY 1986

Mr. Jack Lauber Roussel Uclaf Hoechst-roussel Agri-Vet Co. Route 202-2026 PO Box 2500, Bedm. 31 Somerville, NJ 08876-1258

Dear Mr. Lauber:

Subject: Registration Application

Deltamethrin 4% Collar EPA File Symbol 68451-R

Your Letter Dated August 11, 1993

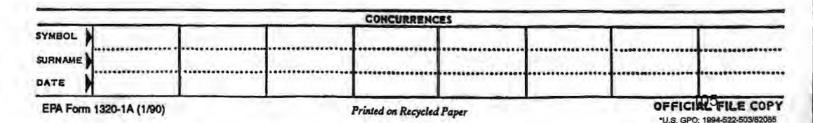
The product referenced above will be acceptable for registration under FIFRA sec. 3(c)(7)(A) and (B) provided that you agree in writing to:

1. Submit a summary of your efficacy data demonstrating control of fleas and ticks that are consistent with labeling claims. We request this information be submitted to the Agency within 3 months of the date of this registration notice.

And make the following labeling changes:

2. Revise your Statement of Practical Treatment as follows: IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF ON EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Refer to your copy of the May 16, 1995 Precautionary Review Section review for complete information on your product's acute toxicity profile.



- 3. Revise the heading so it reads Hazards to Humans and Domestic Animals. Also, revise the statements so that they read "Harmful if swallowed or absorbed, through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Do not use this product on cats (note: this sentence should appear in bold). Do not use on puppies less than 3 months of age.
- 4. Revise the statements regarding sick or convalescing dogs to read as follows: "This product is not recommended for use on debilitated, aged, pregnant, medicated, or pregnant animals. Consult a veterinarian before using."
- 5. Delete the statement "Initial use of collar is to be in conjunction with dip or dust." Your product should not depend on other products for efficacy. If this collar is part of a flea control program you should list specific (active ingredient) products to be used. Depending on the type of product(s) chosen and the rate of application we may require additional domestic animal safety and/or efficacy, data.
- 6. Delete "..and deer tick (Ixodes scapularis) which may carry Lyme disease." This is a public health claim which requires the submission of supportive efficacy data.
- 7. Delete the claims "new molecule first collar formulated with a pyrethroid" and "one of the longest lasting flea and tick killers...etc." There are other pyrethroid collars registered. Also words or phrases implying that a product possesses unique characteristics because of its composition are not acceptable. You may use the word new or new formulation for a period of six months following the notice of registration.
- 8. Under the signal word we recommend revise "Keep out of the reach of children" to "Do not let children play with this collar."
- Singularize the term Active Ingredients. Your product contains only one active ingredient.
- 10. Delete the asterisk and have the chemical name follow the common name in the ingredient statement. Deltamethrin was registered in the U. S. two years ago and is not considered a commonly recognized name in the U. S.

You will submit three copies of your final printed labeling before you release the product for shipment.

The "Notice of Registration" will be issued when you have agreed in writing to the conditions stated above and submitted corrected labels.

THIS LETTER DOES NOT CONSTITUTE REGISTRATION, AND THE PRODUCT MAY NOT BE LAWFULLY MARKETED UNTIL IT IS REGISTERED.

Please respond within 75 days from the date of this letter stating your intentions to comply with the information/data requests cited above. If no resubmission is received during the 75-day period, the application will be administratively withdrawn.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide-Rodenticide Branch Registration Division (7505C) Deschmusion-514

* 8-1-9

Hoechst-Roussel Agri-Vet Company

Route 202-206 Bedm.1 PO Box 2500 Somerville, NJ 08876-1258 Telex 833-449 Cable Hoechstus, Somerville, NJ

Telephone (908) 231-3426 Fax (908) 231-4462

August 22, 1995

Mr. George T. LaRocca (PM 13)
Office of Pesticide Programs (H7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Subject: Deltamethrin 4% Dog Collar EPA File Symbol 68451-R (previously EPA File Symbol 432-TTO)

Dear Mr. LaRocca:

As the authorized representative and principal contact of Roussel Uclaf, S.A., Division Santé Animale, I am responding to the questions raised in a Product Chemistry Review concerning the Deltamethrin 4% Dog Collar.

By way of background, on August 11, 1993, Roussel Uclaf Corporation (now AgrEvo Environmental Health) submitted a Registration Application (plus supporting information) for the registration of Deltamethrin 4% Dog Collar. The pending registration was assigned EPA File Symbol 432-TTO. On March 23, 1995, the pending registration was transferred to Roussel Uclaf, S.A., Division Santé Animale. The pending registration was assigned EPA File Symbol 68451-R. On April 13, 1995, Mr. John Hebert of your staff provided me with the Product Chemistry Review dated December 29,...

The Product Chemistry Review raised the following requirements:

- 1. Revise the label ingredient statement
- 2. Revise the Confidential Statement of Formula by correcting the CAS # for deltamethrin

Product ingredient source information may be entitled to confidential treatment

- 3. Revise the manufacturing process relative to temperature (Fahrenheit or Centigrade).
- 4. Provide information concerning Corrosion Characteristics, Storage Stability, and Flammability
- 5. Provide additional information concerning three inert ingredients previously not approved for use in dog collars

Our response to these requirements is as follows;

1. Revision of the Label Ingredient Statement

Attached you will find a revised label which positions the ingredient statement as specified in the product chemistry review. The name and address of the registrant was also revised because of the transfer of the pending registration.

2. Revision of the Confidential Statement of Formula

While not stated in the product chemistry review, the Confidential Statement of Formula needs to be revised to reflect that the Deltamethrin Technical used in making the Deltamethrin 4% Dog Collar is active as indicated on the Confidential Statement of Formula dated August 11, 1993. Attached you will find a revised Confidential Statement of Formula revised to reflect the In addition, I have corrected the CAS # for deltamethrin and revised the amounts in Sections 13 and 14 to reflect the very slight change in introducing a Deltamethrin Technical of lower concentration, and its slight effect on the concentration of solvent used in making the product. Also, I have revised Sections 1, 2, and 6 to reflect the new registrant Roussel Uclaf, S.A., Division Santé Animale.

3. Manufacturing Process Revision

On page 6, CONFIDENTIAL ATTACHMENT, Volume 1 of the August 11; 1993 submission concerning the Manufacturing Process, all temperatures shown should be ° F. A corrected page is attached.

4. Corrosion Characteristics, Storage Stability, and Flammability

With our submission dated August 21, 1995, we submitted a report which will satisfy the Product Chemistry requirements for Corrosion Characteristics and Storage Stability.

Concerning flammability, the Agency states in its Guidelines Ref. 63-15 (40 CFR 158.190) that flammability data is "required if the product contains combustible liquids". Deltamethrin 4% Dog Collar does not contain any liquid combustible ingredients. It is not flammable and consequently, a flammability test was not performed.

5. Inert Ingredients Not Approved for Use in Dog Collars

Information concerning the three inert ingredients previously not approved for use in dog collars has been submitted to the Agency under separate cover.

If you have any questions or require additional information, please do not hesitate to contact me. Thank you in advance for your help concerning the registration of Deltamethrin 4% Dog Collar.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Attachments

Revised label (5 copies), revised CSF, revised p.6 of CONFIDENTIAL ATTACHMENT pertaining to manufacturing,

СС

L. Ahlman

C. Chieze

A. R. Donoghue

D. Frey

P.-Y. Kravtchenko

R. K. Muser

L. Poly

J. P. Scheid

M. Trausinger

/95 08 17c

110

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

✓,	GUARANTEED WATER PROOF
∀ .	KILLS FLEAS FOR 11 MONTHS
✓	KILLS TICKS FOR 7 MONTHS
. 🗸	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
✓	ODORLESS
. ✓	FITS DOGS WITH NECKS UP TO 21"
·	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA
	& TICK KILLERS AVAILABLE FOR USE ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENT:
Deltamethrin*
INERT INGREDIENTS
Total

Percent by Weight 4.0% 96.0% 100.0%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA Reg. No. 68451- EPA Est. No. Aug. 22, 1995

Roussel Uclaf, S.A. Division Santé Animale 102 route de Noisy 93235 Romainville, France

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

NOV 1 6 1993

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

EPA Id# 000432-TTI. Deltamethrin: Review of a domestic animal safety study with the product

"Deltamethrin 3% Collar".

TOX CHEM No.: 463B PC No.: 097805

Barcode No.: D194602 Submission Non A S446520

FROM:

John Doherty

Section IV, Toxicology Branch I Health Effects Division (7509C)

TO:

George LaRocca/John Hebert

Product Manager #13

Registration Division (7505C)

THROUGH:

Marion Copley, DVM, Section Head

Section IV, Toxicology Branch I

Health Effects Division (7509C)

CONCLUSION

The domestic animal safety study with the product Deltamethrin 3% Collar was reviewed and determined to be ACCEPTABLE. No reactions to treatment were noted when one collar (4% active ingredient worn for six months), four collars (3% active ingredient worn for three months, or 4% active ingredient worn for six months) were worn.

The product has been demonstrated to be safe for adult dogs. If the registrant wishes to register the product for use on dogs less then 3 months of age an additional study using puppies of defined age will have to be presented.

II. Action Requested

The Roussel Uclaf Company (refer to letter from Sharon M. Johnson dated July 9, 1993) has submitted a domestic animal safety study (MRID No.: 428890-06) with dogs to support the registration of the product Deltamethrin 3% Collar. The study was reviewed and the following comments apply.

III. Toxicology Branch Comments

- 1. The study was determined to be ACCEPTABLE and to demonstrate the safety of the product to <u>adult</u> (see item 2 below) dogs. The study demonstrated that there were no effects of wearing 3 or 4 collars equivalent to 3 or 4 times the recommended usage rate for up to six months. Refer to the DER attached.
- 2. The age of the test dogs was not specified in the study report. Therefore, the product is considered to have been demonstrated to be safe for use on <u>adult</u> dogs (greater than 3 months of age). The product label should thus include in the precautionary statement <u>for use on dogs of greater than 3 months of age only.</u> Or do not use on puppies less than 3 months of age. [Note: This precautionary statment is already included on the draft label dated July 20, 1993.]

If the registrant wants to use the product on puppies less than 3 months of age, the registrant will have to provide the exact ages of the dogs used in the existing study and demonstrate that treatment was initiated at a specified age less than 3 months.

Alternatively, the registrant will have to submit a second study in which the treated puppies are of a defined age. For example, if one month old puppies are treated, and the study demonstrates the 3 fold safety factor in which no reactions are noted, the product label can be amended to include for use of puppies greater than one month of age. If this study is conducted, the puppies should not have to treated for more than two weeks and the ChE and AChE assays should not have to be included.

IV. <u>Studies Reviewed</u>

Study Identification	Material	MRID No.:	Results	Classification
86-1. Domestic animal safety study-dogs. Hazleton.# HWA 2623-103. April 11, 1993	3% and 4% deltamethrin containing collars from lots 1103 (3%) and 1104 (4%).	428890-06	No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months). Mongrel purpose bred dogs. Control (4 collars without delta-methrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.	ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

[86-1. Dogs 4% collars/1993]

Reviewed by: John Doherty June 11/15/93

Section IV, Toxicology Branch I (7509C)

Secondary reviewer: Marion Copley, DVM Section IV, Toxicology Branch I (7509C)

Mour Copley 1/12/93

DATA EVALUATION REPORT

STUDY TYPE: 86-1. Domestic animal safety study (6 month-dogs)

MRID NO.: 428890-06.

TOX. CHEM. NO.: 463B

PC No.: 097805

TEST MATERIAL: 3% (from lot No.: 1103) and 4% (from lot 1104) deltamethrin fortified dog collars.

STUDY NUMBER (S): HWA 2623-103 and RBT No.: 91-135.

SPONSOR: Roussel Bio Corporation, Lincoln Park, New Jersey

TESTING FACILITY: Hazleton Washington, Inc.

TITLE OF REPORT: "6-Month Deltamethrin Flea and Tick Collar Safety Study in Dogs"

AUTHOR(S): Dan W. Dalgard, D.V.M.

REPORT ISSUED: April 11, 1993

STUDY DATES (in life): Initiation: November 27, 1991, Termination June 29, 1992.

CONCLUSIONS:

No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months).

Mongrel purpose bred dogs. Control (4 collars without delta-methrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.

Classification: ACCEPTABLE. The study satisfies the requirement for a domestic animal safety study for adult dogs. An additional study may be required to support the use of this product on puppies less than three months of age.

Quality Assurance Statement: Provided. Good Laboratory Practice Statement: Provided. All dogs survived the experiment and no treatment related findings were noted.

2. Body weight and feed consumption.

Body weight and feed consumption were reportedly assessed weekly. The study author maintains that there were no compound related effects on these parameters.

TB-I considers that the body weight and feed consumption data showed variations for which interpretation was confounded by the fact that the dogs were mongrels and of different sizes and there were only four dogs/sex/treatment group. Inspection of the growth curve for females (refer to Figure 3, photocopied from the study report attached) supports the conclusion of the study author. The male group wearing only one collar had a higher rate of growth than the other dogs. The report, however, asserts that this is related to the dogs being mixed and mongrels. Since the dogs wearing four collars (with either 3 or 4% deltamethrin) did not also show indications of similar increased weight gain, TB-I concurs that the weight gain pattern for the group wearing only one collar was not affected by the presence of the deltamethrin in the collar.

There also appeared to be an increase in feed consumption in the dogs (both sexes) wearing 4 collars with 4% deltamethrin in the later weeks of the study (refer to Figure 3 photocopied from the study report attached). TB-I does not consider that the apparent increase is conclusively related to treatment.

3. Clinical Hematology and Biochemistry

Samples of blood were taken from the jugular vein from fasted dogs on days -7, -6, -3, 2, 4, 8, 15, 22, 29, 54 and 89 and 180. for plasma ChE and RBC AChE. Blood samples for days -13, 25, 51 and 86 and 177 were also taken for hematology and serum chemistry.

A. <u>Hematology</u>. The following hematology parameters were reportedly investigated.

cell morphology corrected leukocyte count erythrocyte count erythrocyte sedimentation rate hematocrit

hemoglobin leucocyte count leucocyte differential platelet

No consistent compound related effects were noted on any of these parameters.

REVIEW

Experimental Constants:

<u>Test Material:</u> Deltamethrin impregnated dog collars containing 3% (from lot #1103) or 4% (from lot #1104) and placebo collars without deltamethrin (lot #110C) obtained from the Roussel Uclaf Company.

<u>Test System:</u> Purpose bred mongrel dogs with both short and long hair were obtained from the Hazleton Research Products, Inc. Cumberland, Virginia. The exact age of the dogs at initiation of dosing (age of application of the collars) was not referenced in the report.

Basic Experimental Design

Four groups of 4/sex dogs which consisted of a control (placebo collar), low dose (usage rate or one collar of 4% deltamethrin, actually slightly greater than the usage rate of a 3% collar), mid dose (4 collars of 3% deltamethrin) and high dose (4 collars of 4% deltamethrin). The dogs were scheduled to wear their collars for six months. After three months, the mid dose group was terminated because there were no reactions noted in any group. The control, low and high dose groups continued for the scheduled six months.

Analytical Chemistry

- 1. Release rates of deltamethrin from the collars. Sections of the 3% and 4% collars were removed and analyzed for deltamethrin at pretest, at three and six months to determine the rate of release from the matrix. The Analytical report is in Appendix 11. In summary the analytical data were shown to have release rates 120 ug/collar/day for the 3% collar at the 3 month interval. The 4% collars were shown to have release rates of 40 and 251 ug/collar/day at the 3 and 6 month intervals.
- 2. Blood levels of deltamethrin. The blood was sampled from the dogs wearing only one collar on days 25, 51, 86 and 177 and analyzed for deltamethrin content. The limit of assay was said to be 5 ng/ml. No detectable deltamethrin was evident at days 25, 51 and 86. Although some evidence of < 5 ng/ml was noted for three dogs at day 177, the study report did not consider these readings actual (referring to them as incidental). TB-I concurs and does not consider that wearing a single collar resulted in significant levels of deltamethrin in the blood.

Assessments and Results

1. Survival and clinical signs.

The dogs were reportedly examined twice daily for mortality and once daily for behavioral reactions. In addition, a staff veterinarian examined the dogs on days 1, 8, 26, 88 and 179 (in addition to two pretreatment examinations) for dermatological and clinical evaluations including heart and respiratory rate and body temperature recordings.

B. Serum Chemistry

alanine aminotransferase (ALT albumin albumin/globulin ratio alkaline phosphatase aspartate aminotransferase blood urea nitrogen calcium chloride creatine kinase

creatinine
globulin
glucose
inorganic phosphorous
potassium
sodium
total bilirubin
total protein
RBC ACh F
Plasma Ch E

No consistent compound related effects were noted on any of these parameters.

There were some instances on <u>increased</u> RBC AChE (including in the preapplication period) and plasma ChE. Increases in the activity of these enzymes is not a recognized toxicity response. Since there was no inhibition of these enzymes and the increases were not related to the quantity of the collars worn, it is concluded that the treatment did not affect these enzymes. More oper, ChE and AChE are not recognized as being inhibited by pyrethroids such as deltamethrin.

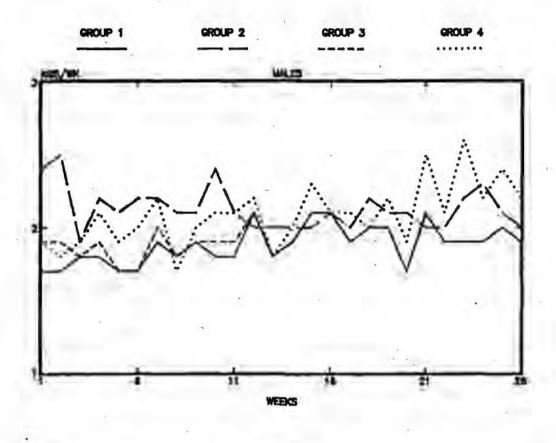
No necropsy was performed and is not considered necessary.

CONCLUSION (Study). The study is considered ACCEPTABLE. No additional domestic animal safety studies are required at this time. The study supports the following "one liner":

No reactions to wearing collars at 3X (for three months) and 1X and 4X (for six months).

Mongrel purpose bred dogs. Control (4 collars without deltamethrin), deltamethrin treated collars: 4%, 1 collar for 6 months; 3%, 4 collars for three months and 4%, 4 collars for six months.

FIGURE 3 - MEAN FOOD CONSUMPTION



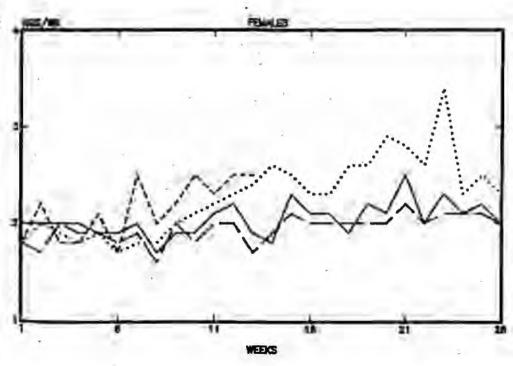
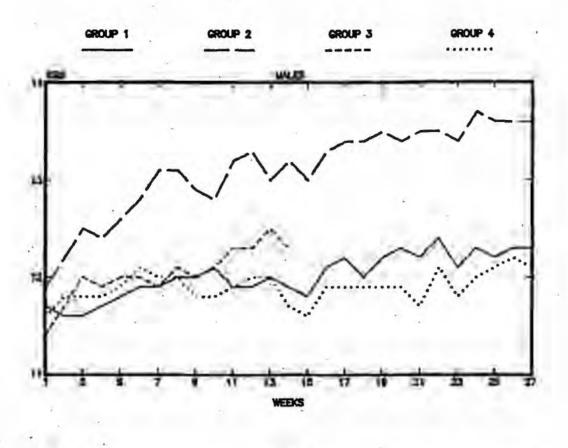
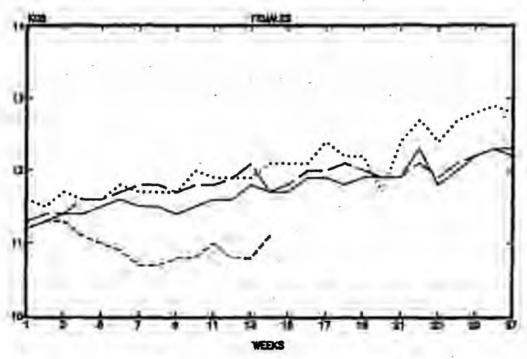


FIGURE 2 - MEAN BODY WEIGHTS







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPTIONAL	FORM	99	(7-90)
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6-23-)8 ITTAL #01

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GENERAL SERVICES ADMINISTRATION

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA File Symbols: 432-TTI / 432-TTO

From:

Mark J. Perry, Biologist Precautionary Review Section Registration Support Branch Registration Division (7505W)

45P6-95

To:

G. LaRocca, PM-13 / J. Hebert

Registration Division (7505C)

Applicant: Roussel-Uclaf Corp.

95 Chestnut Ridge Road Montvale, NJ 07645 908-231-4462

FORMULATION FROM LABEL:

Total:

100%

BACKGROUND

Roussel-Uclaf Corporation submitted acute oral, acute dermal, eye irritation, dermal irritation and dermal sensitization studies, as well as an acute inhalation waiver request for review. The studies were performed with the Deltamethrin 4% Collar (EPA File Symbol 432-TTO); the registrant has requested that these studies also support registration of the Deltamethrin 3% Collar (EPA File Symbol 432-TTI). Both products are insecticidal dog collars containing deltamethrin as the only active ingredient.

The performing laboratory is Stillmeadow, Inc., and the assigned MRID numbers are 428890-01 through 428890-05.

RECOMMENDATIONS

- 1. Acute Oral; Category III / Acceptable
- 2. Acute Dermal; Category III / Acceptable

An impermeable material, such as plastic, is recommended for semi-occlusion in dermal toxicity studies.

3. Acute Inhalation; Waiver Accepted

PRS does not believe that this product poses a significant inhalation hazard.

- 4. Eye Irritation; Category III / Acceptable
- 5. Dermal Irritation; Category IV / Acceptable
- 6. Dermal Sensitization; Non-sensitizer / Acceptable

The study report failed to specify that the concentration selected for induction and challenge was the highest achievable concentration after moistening.

More detailed positive control data was obtained from the performing laboratory (attached). Although the positive control study employed the same concentration for induction and challenge, the data does demonstrate a sensitizing response.

LABELING

- 1. The recommended signal word is "caution."
- 2. The recommended statements of practical treatment are as follows:

IF SWALLOWED: Call a physician or poison control center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

3. The recommended precautionary statements are as follows:

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

4. The signal word should appear on a separate line just below the child hazard warning ("Keep out of reach...").

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (81-1)

Reviewer: M. Perry

Report Date:3/11/92

Report No.:8668-92

Product Manager: 13 MRID No.: 428890-01

Testing Facility: Stillmeadow

Author(s):J. Kuhn

Species: Rat

Age: Young adult Weight: 175-243 g Source: Harlan SD

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Conclusion:

1. LD₅₀ (mg/kg): Males= 4218 mg/kg

Females= 3600 mg/kg
Combined= 3920 mg/kg

2. The estimated LD_{50} is 3920 mg/kg.

3. Tox. Category: III Classification: Acceptable

Deviations from 81-1: None

Results:

200120324	(Number Killed/Number Tested)			
Dosage mg/kg	Males	Females	Combined	
2500	0/5	0/5	0/10	
3500	1/5	2/5	3/10	
5050	4/5	5/5	9/10	

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (81-2)

Reviewer: M. Perry Report Date: 2/21/92

Report No.:8669-92

Product Manager:13

MRID No.: 428890-02

Testing Laboratory: Stillmeadow

Author(s):J. Kuhn

Species: Rabbit

Weight: 2.0-2.6 kg Source: Ray Nichols

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Summary:

1. LC₅₀ (mg/kg): Males= --

Females= --

Combined 2020 mg/kg

The estimated LD₅₀ is greater than 2020 mg/kg.

3. Tox. Category: III Classification: Acceptable

Deviation From 81-2: See recommendations

Results:

Reported Mortality

a she san a care.	(NUMBER KILLED/NUMBER TESTE		
DOSAGE mg/kg	Males	Females	Combined
2020	0/5	0/5	0/10

DATA REVIEW FOR SKIN IRRITATION TESTING (81-5)

Reviewer: M. Perry

Report Date: 2/11/92

Report No.:8671-92

Product Manager: 13

MRID No.: 428890-04

Testing Laboratory: Stillmeadow

Author(s): J. Kuhn Species: Rabbit

Age: Young adult

Sex: 3 male, 3 female

Weight: --

Dosage: 0.5 g

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Summary:

1. The Primary Irritation Index= --

Toxicity Category: IV

Classification: Acceptable:

Deviations From 81-5: None

Results: No irritation was reported in any animal during the observation period.

DATA REVIEW FOR SKIN SENSITIZATION TESTING (81-6)

Product Manager: 13 MRID No.: 428890-05 Reviewer: M. Perry Report Date: 3/16/92

Testing Laboratory: Stillmeadow

Report No.: 8672-92

Author(s): J. Kuhn Species: Guinea pig

Weight: 280-370 g Source: Harlan SD

Test Material: Deltamethrin 4% Collar (reduced)

Positive Control Material: DNCB

Quality Assurance (40 CFR 160.12): Present

Method: Buehler

Summary:

 According to the study results, this Product is not a dermal sensitizer.

2. Classification: Acceptable

Deviation From 81-6: See recommendations.

Results: No irritancy response was reported in the test or naive control animals at challenge.

ACUTE TOX ONE-LINER

1. PC CODE: 097805

2. CURRENT DATE: 5/12/95

3. TEST MATERIAL: Deltamethrin 4%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox.	Core Grade
81-1, Rat, Still- eadow, 8668-92, 3/11/92	428890-01	LD50 = 3920 mg/kg	III	· A
81-2, Rabbit, Still- meadow, 8669-92, 2/21/92	428890-02	LD50 2020 mg/kg	III	A
81-4, Rabbit, Still- meadow, 8670-92, 2/12/92	428890-03	Irritation cleared by 72 hrs.	III	A
81-5, Rabbit, Still- meadow, 8671-92, 2/11/92	428890-04	No irritation reported	IV	A
81-6, Guinea pig, Stillmeadow, 8672-92, 3/16/92	428890-05	Non-sensitizer		A

Core Grade Key:

A' = Acceptable

S = Supplementary

U = Unacceptable

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (81-4)

Reviewer: M. Perry

Report Date: 2/12/92

Report No.:8670-92

Product Manager: 13
MRID No.: 428890-03

Testing Laboratory: Stillmeadow

Author(s): J. Kuhn Species: Rabbit

Sex: 3 female, 3 male

Weight: --

Source: Ray Nichols

Dosage: 50,4 mg

Test Material: Deltamethrin 4% Collar (reduced)

Quality Assurance (40 CFR 160.12): Present

Summary:

1. Toxicity Category: III

2. Classification: Acceptable

Deviations From 81-4: None

Results: All "positive" scores cleared between 24 and 72 hours post dosing.

DELTAMETHRIN 3% COLLAR

FLEA & TICK COLLAR FOR DOGS

		1	GUARANTEED WATER PROOF
		1	KILLS FLEAS FOR 6 MONTHS
		1	KILLS TICKS FOR 4 MONTHS
	5	· •	NEW MOLECULE - FIRST COLLAR FORMULATED WITH PYRETHROID
1		1	ODORLESS
		1	FITS DOGS WITH NECKS UP TO 21"
	10.1	1	GUARANTEED OR YOUR MONEY BACK
		1	ONE OF THE LONGEST LASTING FLEA
100			& TICK KILLERS AVAILABLE FOR USE ON DOGS
		1	WETTING WILL NOT IMPAIR COLLARS EFFECTIVENESS
		1	MAY BE WORN WITH REGULAR COLLAR
		1	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	3.00%
Inert Ingredients	97,00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

EPA EST. NO.

CODE

Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645

DELTAMETHRIN 3% COLLAR

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 6 Month Flea Killer GUARANTEED 4 Month Tick Killer

Deltamethrin 3% Collar provides full season, 6 month flea killing power (and 4 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on pupples less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 3% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 3% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 3% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 4 months. If ticks are a problem, this collar should be worn continuously.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 3% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.

REG. NO: 00432-TTO

Submission: 8452561

FILE SYMBOL: D196505

PRODUCT CHEMISTRY REVIEW FOR END USE PRODUCTS

PRODUCT NAME: Deltamethrin 4% Collar Company: Roussel Uclaf Corp.

TO: 13 George LaRocca/John Hebert

FROM: Shyam B. Mathur, Chemist Shuertur 12/29/9

THRU: Harold Podall, Section Head 11 Podell 12/29/9>

EMICAL: 097805 Deltamethrin

MRID NOS. Series 61(428935-01), Series 62(428935-02), Series 63(428935-03)

Food Use () Non Food Use (X)

Inerts cleared: c () d () e () yes (X) no ()

Inerts List 1 () Other ()

NOTE: Inerts

are not cleared. See ATTACHMENT-31

Please provide the requested information for the following checked items:

- [] Submit the specific chemistry data for your product.
- [] If submitted earlier, provide MRID Number(s).
- 2. [] Your product is not sufficiently similar to the product you referenced.
- 3. In reference to the Confidential Statement of Formula (CSF), please provide the following information of your product:
 - [] a) pH of a specified water dilution.
 - [] b) Density

- [] c) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate.
- [] d) The upper and lower certified limits of the individually added inerts.
- 4. Based on the current CSF (dated), your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.
- 5. Provide the chemical identify of all components, the percentage composition, CAS Registry Numbers, and Material Safety Data Sheet (two copies) for the following compounds:
- 6. In the proposed labeling, provide the following information:
 - [] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [] PR Notice 84-1 for non-aerosol containers for houses and institutional uses of [] PR Notice 83-3 for all other uses.
 - [] b) Add the heading to the label per 40CFR§172-6(a)1.
 - [] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as extremely Flammable (because your product contains flammable propellents). 40CFR§156.10(i)2(ix).

[] d) If the solvent has insecticidal activity provide the EPA Registration Number, if does not it should be removed from the active ingredient statement and added to the total percentage of the inert ingredients.

[] e) Add a footnote to the inert ingredients indicating: Contains petroleum distillates, xylene or xylene-range aromatic solvent.

 f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the physical or Chemical Hazards heading;

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

- [X] g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.
- 7. In reference to the product specific data requirements, provide the following information:
 - [] a) Statement of Composition: A complete description of the manufacturing formulation process. Describe equipment used, mixing time, temperature, pressure, etc. The Registrant described the full formulation procedure for this product; the process, the quantities and the order of addition is described in <u>Attachment-1</u>. (MRID No. 428935-01)

- [] b) Discussion of Formation of Unintentional Ingredients: The Registrant provided following information on this topic[MRID No.428935-01]: No unintentional inert ingredients are introduced in the blending or the filling processes. No unintentional inert ingredients are introduced by the market containers or by storage in them.
- [] c) Certification of Limits: Upper and lower limits or each active and individually added inert component. The Registrant submitted a CSF (dated 08/11/93) for Basic formulation of the product.
- [] d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s). The Registrant submitted data on Series 62 under MRID No. 428935-02). See Attachment-2.

Series 63: MRID No. 428935-03

- [] e) Color: In common terms: White [SOP C-30]
- [] f) Physical State: Solid [SOP C-31]
- [] g) Odor: Odorless [SOP C-33]
- [] h) Density/Sp. Gravity: 72 lbs/cubic foot to 88 lbs/cubic foot [SOP C-35]
- [] i) pH: Not Applicable. The product is not dispersible in water.
- [] j) Oxidizing or Reducing Action: This product does not have the potential to act as a strong oxidizing or reducing agent.
- [] k) Explodability: This product possesses no explosive potential.
- [] 1) Viscosity: Not Applicable, the product is a solid.
- [] m) Miscibility: Not applicable as the product is not emulsifiable and is not intended to be diluted with both water and petroleum distillate.
- [X] n) Corrosion Characteristics: The Registrant did not provide any data on this topic.
- [] o) Dielectric Breakdown Voltage: NA as the product is not intended to be used around electrical equipment.

Product ingredient source information may be entitled to confidential treatment

-5-

- [X] p) Storage Stability: The Registrant did not submit any data on this topic.
- [X] q) Flammability: NA. The product is solid. NOTE: This needs further explanation
- 8. [] The following is the regulatory status of the inert ingredients under 40CFR 180.1001 for the exemption of the requirement of a tolerance.
- 9. Other

Note to PM: Inter-office

Please notify the Registrant :

-). To correct the label as described in 6(g)[40CFR§156.10(g)]
- (2). To submit data on Storage stability(7p) and corrosion characteristics (7n).
- (3). To ask the Registrant whether the Flammability test was done with this product or not? The product being solid does not mean that it can not be Flammable.
- (4). To use same units for temperature(C or F)during describing the formulation process(Series 61-2). Request them to provide information on it, mixed units were used when the process is described (MRID No. 428935-01).
- (5). To correct the CAS No. of the AI Deltamethrin in the CSF submitted 8/11/93.

(6).

(7).

TABLE 1: SUMMARY OF PRODUCT CHEMISTRY DATA REQUIREMENTS

GLR #	TITLES	
Series 167)	61-Product Identity and Composition (40CFR158.155, 160, 162, 165	&
61-1	Product Identity & Disclosure of Ingredients	A
61-2	Description of Starting Materials & Manufacturing Process	A
61-3	Discussion of Formation of Impurities	A
	62-Analysis and Certification of Product Ingredients (40CFR158.1 180)	70,
62-1	Preliminary Analysis of Product Samples	NA
62-2	Certification of Ingredient Limits	A
62-3	Analytical Methods to Verify Certified Limits	A
Seri	les 63-Physical and Chemical Characteristics (40CFR158.190)	
63-2	Color	A
63-3	Physical State	A
63-4	Odor	A
63-5	Melting Point	NA
3-6	Boiling Point	NA
63-7	Density, Bulk Density, or Specific Gravity	A
63-8	Solubility	NA
63-9	Vapor Pressure	NA
63-10	Dissociation Constant	NA
63-11	Octanol/Water Partition Coefficient	NA
63-12	рн	A
63-13	Stability	NA

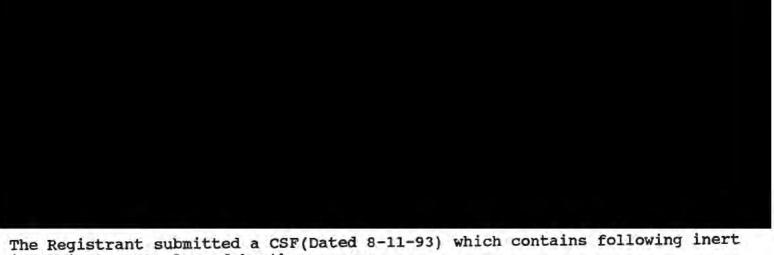
63-14	Oxidizing Or Reducing Action		A
63-15	Flammability		A(?)
63-16	Explodability		A
63-17	Storage stability		DG
63-18	Viscosity		NA
63-19	Miscibility		NA
63-20	Corrosion Characteristics		DG
9- 21	Dielectric Breakdown Voltage		NA
A	- Acceptable	Reviewer	
W	/ - Waived		
N	A - Not Applicable	Section Head	
	G - Data Gap (?) - Acceptable with Reservations	Date:	

Confidential Statement of Formula may be entitled to confidential treatment

ATTACHMENT-1

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

61-1. Product Identity & Disclosure of Ingredients MRID No. 428935-01)



ingredients not cleared by the agency:

ATTACHMENT-1 Contd....

DP BARCODE D196505 SUBMISSION S452561 REG. No. 432-TTO CHEMICAL 097805 Deltamethrin PRODUCT Deltamethrin 4% Collar COMPANY Roussel Uclaf Corporation.

61-2. Description of Beginning Material & Manufacturing Process (MRID No. 428935-01)



Manufacturing Process:

ATTACHMENT-2

<u>DP BARCODE</u> D196505 <u>SUBMISSION</u> S452561 <u>REG. No.</u> 432-TTO <u>CHEMICAL</u> 097805 Deltamethrin <u>PRODUCT</u> Deltamethrin 4% Collar <u>COMPANY</u> Roussel Uclaf Corporation.

Series 62. (MRID No. 428935-02)

62-1. Preliminary Analysis This product is not produced by an integrated formulation system, therefore, preliminary analysis is not required [40CFR§158.170].

62-2. Certification of Ingredient Limits

See the CSF given in Series 61-1.

62-3. Analytical method to verify certified limits:

Determination of Deltamethrin in collars:

the amount of the AI in the collar is determined by using reversed phase HPLC system. A portion of the collar is sliced into very thin crossections, then extracted (using a Ultrasonic bath) with acidified acetonitrile. The solution was then filtered and injected into stabilized HPLC system. Results are quantified using peak area measurements with an external standard.

ruitable liquid chromatograph equipped with a UV detector and electronic equipped with a UV detector equipped w

Column: Supelco LC-18, 25 cm length, 2.1 mm ID, 5 micron particle size.

Detector: 254 nm (UV wavelength)

Mobile Phase: 80% Mobile phase A[mix 99.8% acetonitrile and 0.2% glacial acetic acid and filter through 0.22 μ Nylon 66 filter and degas]

20% Mobile phase B[mix 99.8% deionized wtaer and 0.2% glacial acetic acid and filter through 0.22 μ Nylon 66 filter and degas].

Flow Rate: 0.35 ml/ min.

Chart speed: 0.5 cm/min.

Run time: 20 min.

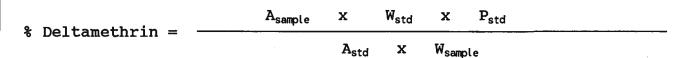
Sample loop volume: 5 μ l

ATTACHMENT-2 Contd....

<u>DP BARCODE</u> D196505 <u>SUBMISSION</u> S452561 <u>REG. No.</u> 432-TTO <u>CHEMICAL</u> 097805 Deltamethrin <u>PRODUCT</u> Deltamethrin 4% Collar <u>COMPANY</u> Roussel Uclaf Corporation.

Series 62. (MRID No. 428935-02)

Calculations:



A_{sample} = average peak area of deltamethrin in sample chromatogram

A_{std} = average peak area of deltamethrin in reference standard chromatogram

 W_{std} = weight of deltamethrin standard

 W_{sample} = weight of collar sample

Fid = % purity of deltamethrin standard.

Inert ingredient information may be entitled to confidential treatment

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

ATTACHMENT 3

cr#: 93-0518

TEL.:(<u>)308-2</u> CSF ATTACHE SLYES NO			
CSF ATTACHE SAYES NO		25/3/20 R	REQUEST DATE: 12 /28/97 OOM: MAIL CODE: H75050
YES NO		(DIV_/BR_/SEG.)	the state of the s
Оио			
544		lete Item A and the chemic	
	If CSF is not attached co	omplete Items A through C	
THE RESERVE OF THE PARTY OF THE	1116 to 1110 to 1		
	ON REQUIRED:	*	
Check Applicable	integery	C4 F F 4 VI	Towns Towns House (a)
		ption Status For Food-Use	mert ingredient(s)
	CC for Non-Food Use In		
Provide 1	PCC for Active Ingredient	1(8)	
		ble for Use in Formulation	
Other (D		able for Use in Formulation	
U Other (L	eacribe):		
. INGREDIEN	I INFORMATION:		
. HIGKEDIE!	I III ORMATION.		
C DECEMONDE	PODUCT MEODALTI	ON	
C. PESTICIDE	PRODUCT INFORMATION	ON:	
			49
EPA Reg. No./Fi	le Symbol: 432-TTO		methrin 4% collar
EPA Reg. No./Fi	le Symbol: 432-TTO	ProductName: Delta	metarcy 4% collar Food-Use Pesticide: ☐ YES NO
EPA Reg. No./Fi	le Symbol: 432-TTO	ProductName: Delta	methrin 4% collar Food-Use Pesticide: □ YES NO
EPA Reg. No./Fi	le Symbol: 432-TTO	ProductName: Delta	methrou 4% collar Food-Use Pesticide: ☐ YES NO
EPA Reg. No./Fi Registrant: <u>Ren</u> Percent in Form	le Symbol: <u>432-TTO</u> (SSE) Uclat costs ulation (For Fragrance/D	ProductName: Delta	methrin 4% collar Food-Use Pesticide: ☐ YES NO
EPA Reg. No./Fi Registrant: <u>Ren</u> Percent in Form	le Symbol: <u>432-TTO</u> (SSE) Uclat costs ulation (For Fragrance/D	ProductName: Delta	methrou 4% collar Food-Use Pesticide: ☐ YES NO
EPA Reg. No./Fi Registrant: <u>Reg</u> . Percent in Form ORMATION RI	le Symbol: 432-TTO USSEL Uclat corbo ulation (For Fragrance/D	ProductName: Della	methrin 4% collar Food-Use Pesticide: YES NO
EPA Reg. No./Fi Registrant: Ren Percent in Form ORMATION RI	le Symbol: 432-TTO USSEL Uclat corbo ulation (For Fragrance/D	ProductName: Della constant Oyes only): 4:	
EPA Reg. No./Fi Registrant: <u>Rep.</u> Percent in Form ORMATION RI	le Symbol: 432-TTO USSEL Uclat corbo ulation (For Fragrance/D	ProductName: Della Dyes only): 4: Ingredient No. 2: PCC:	Mey mert
EPA Reg. No./Fi Registrant: Ren. Percent in Form ORMATION RI Ingredient No.	le Symbol: 432-TTO (SSE Uclat corporation (For Fragrance/D	Ingredient No. 2: PCC: TOL. STATUS:	
EPA Reg. No./Fi Registrant: Ren. Percent in Form ORMATION RI Ingredient No.	le Symbol: 432-TTO (SSE Uclat corpo ulation (For Fragrance/D PORTED:	Ingredient No. 2: PCC: TOL STATUS: OTHER INF:	
EPA Reg. No./Fi Registrant: Ren Percent in Form ORMATION RI Ingredient No. STATUS: GAND CON N	le Symbol: 432-TTO USSEL Uclat corpo ulation (For Fragrance/D PORTED: U. C. Compos Of the also	Ingredient No. 2: PCC: TOL. STATUS: FALOR OTHER INF:	
EPA Reg. No./Fi Registrant: Ren Percent in Form ORMATION RI Ingredient No. STATUS: IER INF: Res and Con N Ingredient No.	le Symbol: 432-TTO (SSE Uclat corpo ulation (For Fragrance/D PORTED:	Ingredient No. 2: PCC: TOL STATUS: Fit On OTHER INF: Ingredient No. 4:	
EPA Reg. No./Fi Registrant: Ren. Percent in Form ORMATION RI Ingredient No. : : STATUS: IER INF: No. Ingredient No. :	le Symbol: 432-TTO USSEL Uclat corpo ulation (For Fragrance/D PORTED: U. C. Compos Of the also	Ingredient No. 2: PCC: TOL STATUS: SHOW OTHER INF: Ingredient No. 4: PCC:	
EPA Reg. No./Fi Registrant: Rep. Percent in Form ORMATION RI Ingredient No. STATUS: LINGUIST AND LINGUIST NO. STATUS: STATUS: STATUS:	le Symbol: 432-TTO USSE! Uclat corpo ulation (For Fragrance/D PORTED: d specific Compos of the about ingredient	Ingredient No. 2: PCC: TOL. STATUS: OTHER INF: Ingredient No. 4: PCC: TOL STATUS:	
EPA Reg. No./Fi Registrant: Ren. Percent in Form ORMATION RI Ingredient No. : . STATUS: IER INF: New Ingredient No. : . STATUS:	le Symbol: 432-TTO USSE! Uclat corpo Usse! Uclat corpo Usse! Uclat corpo Uported: Decrete Compos Se of the about I ingredient.	Ingredient No. 2: PCC: TOL STATUS: SHOW OTHER INF: Ingredient No. 4: PCC:	New mert



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAR 23 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Roussel Uclaf, S.A.,
Division Sante Animale
c/o Mr. John J. Lauber
Hoechst-Roussel Agri-Vet Company
Route 202-2026, P.O. Box 2500, Bedm. 31
Somerville, NJ 088760-1258

Dear Mr. Lauber:

Subject: Transfer of Pending Pesticide Registrations From Company Number 432 to Company Number 68451

Pursuant to your request in your letter and transfer agreement of February 14, 1995, we have approved the transfer of the following pending registrations from AgrEvo Environmental Health, Inc., company number 432, to Roussel Uclaf, S.A., Division Sante Animale, company number 68451.

The effective date of these changes is the date of this letter.

	Old EPA	New EPA	
Pending Product Name	File Symbol	File Symbo	I
The state of the s			-
Deltamethrin 4% Collar	432-TTO	68451-R	-
是一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个			
Deltamethrin 3% Collar	432-TTI	68451-E	
are the war to a serious in the serious and th		A A	

The products listed above are pending registrations and therefore cannot be marketed until they have been registered.

The transferred pending registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

By copy of this letter we are informing AgrEvo
Environmental Health, Inc. / of these changes. If you have any
questions about this transfer please call Daria Mills at (703) 2
305-7406.

Sincerely,

John Jamula Chief

Information Resources Section

Information Services Branch

Program Management and Support Div. (7502C)

AgrEvo Environmental Health, Inc.



United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460

X	Registration
110	Amendment
i	Registration Amendment Other

OPP Identifier Number

	Se	ection I				
1. Company/Product Number		2. EPA Product Manager	3.	Proposed Classification		
	432-TT0	George LaRo	cca	J		
4. Company/Product (Name)		PM#	X	None Restricted		
Deltamet	thrin 4%-Collar	13				
5. Name and Address of Appli	carit (Include ZIP Code)			th FIFRA Section 3(c)(3)		
Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645 Check if this is a new address		to:	EPA Reg. No.			
	Sec	tion I I				
1	-	Final printed labels	in response to			
Amendment - Explain bel	ow	Agency letter date				
Resubmission in response	e to Agency letter dated	"Me Too" Applicati	00			
Notification - Explain belo	W. di			115		
		Other - explain bel	ow.			
Material This Product Will Child-Resistant Packaging U	Be Packaged In:	Water Soluble Packaging Yes	2. Type of Containe	er .		
X No	X No	X No	Plastic Glass X Paper	Set A.		
* Certification must be	"Yes," No. per nit Package wgt. container	If "Yes," No. per container		Specify)		
* Certification must be submitted. 3. Location of Net Contents Interpretation	nit Package wgt. container formation 4. Size(s) of tainer 1.1 oz	Package wgt. container Retail Container 5. I	Location of Label Dire	ALC: N		
* Certification must be submitted. 3. Location of Net Contents Int	roit Package wgt. container formation 4. Size(s) of tainer 1.1 oz ffixed To Product X Lithog Paper Stend	Package wgt. container Retail Container 5. I . (1 collar) graph glued illed	Location of Label Dire	ctions		
* Certification must be submitted. 3. Location of Net Contents Int X Label Contents Contents Int K Label Contents Int Conten	formation 4. Size(s) of tainer 1.1 oz ffixed To Product X Lithog X Paper Stend	Package wgt. container Retail Container 5. I (1 collar) graph glued illed tion IV	Location of Label Dire Con Label On Labeling acco	ctions mpanying product)		
* Certification must be submitted. 3. Location of Net Contents Int X Label Contents Int 6. Manner In Which Label Is A	formation 4. Size(s) of tainer 1. 1 oz ffixed To Product X Lithog Paper Stend	Package wgt. container Retail Container 5. I . (1 collar) graph glued illed	On Labeling acco	ctions mpanying product)		
* Certification must be submitted. 3. Location of Net Contents Int X Label Contents Int Manner In Which Label Is A	formation 4. Size(s) of tainer 4. Size(s) of tainer 1. 1 oz Fixed To Product X Lithog Paper Stend Security below for identification	Package wgt. container Retail Container 5. I (1 collar) graph glued illed ction IV n of individual to be contacted, if ne	On Label Dire On Labeling acco	ctions mpanying product) his application.)		
* Certification must be submitted. 3. Location of Net Contents Into X Label Contents Into X Label S. Manner In Which Label Is A. 1. Contact Point (Complete ite Name Sharon M. Jo	formation 4. Size(s) of tainer 1.1 oz ffixed To Product X Lithog Paper Stend Sector Sect	Package wgt. container Retail Container 5. I (1 collar) graph glued illed tion IV n of individual to be contacted, if ner Title Registration Special:	On Label Dire On Label On Labeling acco Cessary, to process the Capital Capita	ctions mpanying product) his application.) ne No. (Include Area Code)		
* Certification must be submitted. 3. Location of Net Contents Into X Label Contents Into X Label Contents Into X Label Is A Content Into X Label Is A Content Into X Label Is A Content Point (Complete ite Name Sharon M. Journal of Contents Into X Label Is A Content Point (Complete ite Name) I certify that the statements I I acknowledge that any knowledge that any knowl	formation 4. Size(s) of tainer 1.1 oz ffixed To Product X Lithog Paper Stend Sec ems directly below for identification have made on this form and all a wingly false or misleading statem	Package wgt. container Retail Container (1 collar) graph glued glied ction IV n of individual to be contacted, if need Title Registration Special: n attachments thereto are true, accurate nent may be punishable by fine or in 3. Title	Cessary, to process the Capital Capita	nis application.) ne No. (Include Area Code) 307–9700 6. Date Application Received		
* Certification must be submitted. 3. Location of Net Contents Into X Label Content Point (Complete itelligible) 1. Contact Point (Complete itelligible) Sharon M. Journal Contents Into X Label Con	formation 4. Size(s) of tainer 1.1 oz X Lithou X Paper Stend Sector Identification And All awingly false or misleading statem	Package wgt. container Retail Container . (1 collar) graph glued filed ction IV In of individual to be contacted, if ner Title Registration Special: In attachments thereto are true, accurate the may be punishable by fine or in	Cessary, to process the Capital Capita	mpanying product is application.) ne No. (Include Area Code 307–9700 6. Date Application Received		

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:
1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4);

3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted:

6. Authorization letter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5×11 inch file. Mockup labels significantly smaller than 8.5×11 inches should be mounted on 8.5×11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application." For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned
 to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Mumber.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.

2. Type of Retail Container - Indicate type of container in which product will be marketed.

5. Location of Met Contents - Specify the net contents of all retail containers for your product. 4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.

Location of Use Directions - Indicate the location of the use directions for your product.

6: Wahner in which label is affixed to product - Indicate the method product label, is attached to retail container.

SECFION IV (Contact Point) - This Section must be completed for all applications for Registration actions is. new products registration, resubmission, "me-too," reregistration, etc. 6. EPA Use Only.



United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460

Registration
Amendment
Other

201011

OPP Identifier Number

	4			
	Section I	7		
Company/Product Number	2. EPA Product		3. Propos	sed Classification
432-TT0	George PM#	LaRocca	X Nor	ne Restricte
. Company/Product (Name)			(A)	, lostricte
Deltamethrin 4% Collar	13			27.20.12.10.10.10
Name and Address of Applicant (Include ZIP Code)		Review. In accordant is similar or id		
Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvele, NJ 07645 Check if this is a new address	to: EPA Reg. No.		entical in compo	Jamon and Iadelin
	Product Name			_
3		ted labels in respons	e to	
Amendment - Explain below		etter dated		
Resubmission in response to Agency letter dated	"Me Too"	Application.		
Notification - Explain below.				
	Other - e	xplain below.	16 1	
Material This Product Will Be Packaged In: hild-Resistant Packaging Unit Packaging	Water Soluble Packagin	a 2. Type	of Container	
Voc* T Yes	- 1 Jan 19 Jan 1			
Yes* X No X No	Yes X No	100	Metal Plastic Glass	
X No If "Yes," No. I	Yes No per If "Yes,"	No. per	Metal Plastic	y)
X No If "Yes," No. pure Certification must be Unit Package wgt. No. pure Contains and Contains	Yes X No Der If "Yes,"	1	Metal Plastic Glass Paper	γ)
Certification must be Unit Package wgt. No. processes a submitted. Location of Net Contents Information 4. Size(Yes X No Der if "Yes," Package wgt. S) of Retail Container OZ. (1 collar)	No. per X X X X X X X X X X X X X X X X X X X	Metal Plastic Glass Paper Other (Specify	
Certification must be Unit Package wgt. No. product W. Label Container 1.1 Manner In Which Label Is Affixed To Product X. I. I.	Yes No Per If "Yes," Package wgt. S) of Retail Container Oz. (1 collar) Lithograph Paper glued Stenciled	No. per X Sontainer 5. Location of X On Lab	Metal Plastic Glass Paper Other (Specifications seel	
Certification must be Unit Package wgt. No. product Value Container Value Cont	Yes No Per If "Yes," Yes," Yes, "Package wgt. So of Retail Container OZ. (1 collar) Lithograph Paper glued Stenciled Section IV	No. per X container 5. Location of X On Lat On Lat	Metal Plastic Glass Paper Other (Specify Label Directions sel peling accompany	ing product
Certification must be Unit Package wgt. Container Container Label Submitted. Label Container Label Is Affixed To Product X X Size(Container Submitted).	Yes No Per If "Yes," Yes," Yes, "Package wgt. So of Retail Container OZ. (1 collar) Lithograph Paper glued Stenciled Section IV	No. per X container 5. Location of X On Lat On Lat	Metal Plastic Glass Paper Other (Specify Label Directions sel seling accompany	ing product
Certification must be Unit Package wgt. Size(Location of Net Contents Information Label Container Manner In Which Label Is Affixed To Product Contact Point (Complete items directly below for identifiame Sharon M. Johnston	Yes X No Der If "Yes," Package wgt. S) of Retail Container OZ. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contact Title Registration Sp	No. per X container 5. Location of X On Lat On Lat Other (Metal Plastic Glass Paper Other (Specifications selecting accompany) Process this app Telephone No. (@01) 307	lication.) (Include Area Cod
Certification must be Unit Package wgt. Container Location of Net Contents Information 4. Size(Label Container L. I Manner In Which Label Is Affixed To Product X Contact Point (Complete items directly below for identifiame Sharon M. Johnston Certification must be Unit Package wgt. Contact Point (Contents Information 4. Size(Container L. I) Contact Point (Complete items directly below for identifiame Sharon M. Johnston Certification must be Unit Package wgt. Contact Point Container L. I Container L. I Contact Point (Complete items directly below for identifiame Sharon M. Johnston Certification M. Johnston M. Johnston Certification M. Johnston M. Johnst	yes X No Der If "Yes," Package wgt. S) of Retail Container OZ. (1 collar) Lithograph Paper glued Stenciled Section IV fication of individual to be contact Title Registration Sp cation d all attachments thereto are true	No. per Sontainer 5. Location of Non Late On	Metal Plastic Glass Paper Other (Specify Label Directions sel peling accompany Telephone No. (201) 30	lication.)
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Product ingredient source information may be entitled to confidential treatment

Formulator's Exemption Statement

Applicant's Name and Address: EPA File Symbol/Registration Number: 432- TT∂

Roussel Uclaf Corporation 95 Chestnut Ridge Road Montvale, NJ 07645 Product Name: Deltamethrin 4% Collar

Date of Confidential Statement of Formula: August 11, 1993

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the following active ingredient(s):

deltamethrin

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another product.
- (3) Indicate by checking (A) or (B) below which paragraph applies:

X

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

		Source
Active Ingredient	Product Name	Registration Number
deltamethrin		
Signature Alaren I.	Name and Title Sharon M. Johnston Registration Specialist	Date August 11, 1993

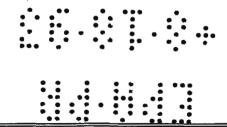
Certification with Respect to Citation of Data

Applicant's Name and Address:		EPA File Symbol/Reg	EPA File Symbol/Registration Number: 432-TTO				
	claf Corpor			Product Name: Delta	methrin 4% Collar		
95 Chestnut Ridge Road Montvale, NJ 07645		Date of Application:	August 11, 1993				
for the san	your produ ne uses, you 8570-27).	uct is a 10 ou do no	00% repackaging of ar t need to submit this	nother EPA-registered pro form. You must submit t	duct that you purch he Formulator's Exe	ase, and is emption Sta	labeled tement
are eff be co	e indicated ects of this required to mposition	, this app product be sub- and inte	Dication is supported that is identical or sub mitted if this application anded uses under the	omitted or cited in the app by all data in the Agency ostantially similar, and that n sought the initial registra e data requirements in e in items 2 and 3 below, t	's files that concerr is one of the types ation of a product of ffect on the date of	n the prope of data that identical or of approval	rties or t would similar of this
2. lo	ertify that, f	or each s	study cited in support	of this application for regi	stration that is an ex	xclusive use	study,
ON	l am the	original s	submitter*; or				
	I have ob	otained th	ne written permission	of the original data submi	tter to cite that stud	ly*	
	ertify that, d	for each	study cited in suppor	t of this application for re	gistration that is no	t an exclus	ive use
a.	M	I am t	he original data subm	itter*; or			•
		l have	obtained the written	permission of the original	data submitter to c	ite that stud	ly*; or
b.		applic section (FIFR/ compe	ation and have offered n 3(c)(1)(D) and 3(c)(3 A); and (b) Commer	companies that have subred to: (a) Pay compensations (b) of the Federal Insectice negotiations to determine the Amount and the Amount and are: (Check one)	ion for those data in ticide, Fungicide an rmine which data a	n accordant nd Rodentic are subject	ce with ide Act to the
			contained in my pro	I on the Pesticide Data Suduct (cite-all method or citeral Offer Statement below	e-all option under S		
			Those companies t method*)	hat have submitted the s	studies which I hav	ve cited (Se	elective
		ata Matri: e-all metl		dies is attached. (Note: a	a Data Matrix is not a	re quired u n	der the
Signature:			Name and 1	Title:	Date:		
Thais	n fl	Me	Sharon M. J Registration		8-11	-83	
				y offer and agree to pay of all of this application, to the		ner	•
Signature:		,	Name and T	Title:	Date:	••••	•

							I	
Product Name	ame: 2. EPA Reg. No./File Symbol:		3. Formulator's Exemption Selected:			4. Page <u>1</u> of <u>3</u>		
	Deltamethrin 4% Collar	432- TT O		YESXNO		· ugo <u></u> o. <u>u</u>		
5. Applicant's No	ame and Address:	6. Application for	Registration Dated:					
95 Chest	Udaf Corporation mut Ridge Road p, NJ 07645	<u>08</u> /_ MO.	11 / 93 DAY YR.	7. Name of Active Inc	gredient(s):	Deltamethrir	1	
8. DATA RE	QUIREMENTS	9. SOURCE	OF DATA SATISFYIN	G REQUIREMENT				10.
8a. Regulation Part 158/ Guideline No.	8b. Name of Test	9a. Submitted By Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	MRID Number, EPA Accession Number or Other EPA Identifying Number
§158.150	PRODUCT CHEMISTRY					-		
61-1	Chemical Identity	х	08-11-93					
61-2	Begin. Materials & Manufacturing Process	х	08-11-93					
61-3	Discussion of Formation of Impurities	х	08-11-93					
62-1	Preliminary Analysis						NA (formualtor's e	xemption)
62-2	Certification of Ingredient Limits	х	08-11-93					
62-3	Analytical Method to Verify Certified Limits	х	08-11-93					
63-2	Color	х	08-11-93					
63-3	Physical State	х	08-11-93					
63-4	Odor	х	08-11-93					
63-5	Melting Point						NA (formulator's e	xemption)
63-6	Boiling Point						NA (formulator's e	xemption)
63-7	Density, Bulk Density or Specific Gravity	х	08-11-93					
63-8	Selubility						NA (formulator's e	xemption)
to the first of th								

1. Product Name	э:	2. EPA Reg. No./File Symbol:		3. Formulator's Exemption Selected:			4. Page <u>2</u> of _	2
	Deltamethrin 4% Collar	432-TTO		YES X	NO		4. Page <u>2</u> 01	<u> </u>
5 Applicant's N	ame and Address:	6 Application to	r Registration Dated:	1E3 <u>. x</u>				
]						
95 Ches	Uclaf Corporation Inut Ridge Road		11 / 93 DAY YR.	7. Name of Active Ingr	redient(s):			
Montvale	o, NJ 07645					Deltamethrin		
8. DATA RE	QUIREMENTS	9. SOURCE	OF DATA SATISFYING	G REQUIREMENT				10.
8a.	8b.	9a.	9b.	9c.	9d.	9e.	9f.	MRID Number,
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§158.150	PRODUCT CHEMISTRY (Cont.)							
63-9	Vapor Pressure						NA (formulator's ex	kemption)
63-10	Dissociation Constant						NA (formulator's ex	kemption)
63-11	Octanol/Water Partition Coeffecient						NA (formulator's ex	kemption)
63-12	рН						NA (not dispersible	with water)
63-13	Stability						NA (formulator's ex	kemption)
63-14	Oxidizing/Reducing Action	х	08-11-93					
63-15	Flammability						NA (does not cont liquids)	ain combustible
63-16	Explodability	X	08-11-93				Ĺ	
63-17	Storage Stability						NA (PR Notice 92-	5)
63-18	Viscosity						NA (not a liquid)	
63-19	Miscibility						NA (not an emulsi	iable concentrate)
63-20	Corrosion Characteristics						NA (not corrosive)	
63-21	Dielectric Breakclown Voltage						NA (not for use are equipment)	ound electrical
								15.4

1. Product Name	Deltamethrin 4% Collar 2. EPA Reg. No./File Symbol: 432-TTO		3. Formulator's Exemption Selected:			4. Page <u>3</u> of <u>3</u>		
5. Applicant's N	ame and Address:		r Registration Dated:	YES <u>X</u>	NO	_		
95 Chest	Uclaf Corporation tnut Ridge Road e, NJ 07645	<u>08</u> / MO.	11 / 93 DAY YR.	7. Name of Active Ing	redient(s):	Deltamethrin		
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§158.340	TOXICOLOGY							
81-1	Acute Oral LD ₅₀ - Rat	x	07-09-93				ļ	
81-2	Acute Dermal LD ₅₀ - Rat/Rabbit	х	07-09-93					
81-3	Acute Inhalation LC ₅₀ - Rat	х	07-09-93				Waiver Request	
81-4	Primary Eye Irritation - Rabbit	х	07-09-93					
81-5	Primary Dermal Imitation	x	07-09-93					
81-6	Dermal Sensitization	×	07-09-93					
81-7	Acute Delayed Neurotoxicity - Hen						NA (not an organo	phosphate)
86-1	Domestic Animal Safety	x	07-09-93	T				



FLEA & TICK COLLAR FOR DOGS

✓	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
✓	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH
	PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA
	& TICK KILLERS AVAILABLE FOR USE
	ON DOGS
✓	WETTING WILL NOT IMPAIR COLLARS
	EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

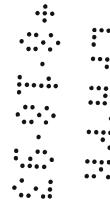
See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

EPA EST. NO.

CODE



FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Deltamethrin 4% Collar contains Deltamethrin insecticide, one of the longest lasting flea and tick killers available for use on dogs. The Deltamethrin 4% Collar has been specially formulated using patented insecticide release technology. Because of the long duration of activity of the Deltamethrin 4% Collar, maximum effectiveness may not occur for 2-3 weeks after collar placement. Initial use of collar is to be in conjunction with dip or dust. Fleas (Ctenocephalides sp.) on the dog will be killed and ones which are present in the dogs environment that may reappear on your pet will be killed. Collar will kill ticks including Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis) which may carry Lyme disease. Ticks appear on dogs in 3 stages. In the 1st two stages, ticks are smaller than a matchhead and are difficult to see. The collar will also control these immature stages. This collar provides effective tick control for up to 7 months. If ticks are a problem, this collar should be worn continuously.

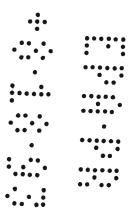
Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FTIS ALL-TRIM TO SIZE

This collar is designed to fit 99% of all dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



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Inert Ingredients	96.00%
	100.00%

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NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG. NO. 432-

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FLEA & TICK COLLAR FOR DOGS

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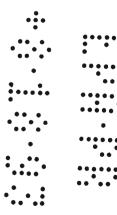
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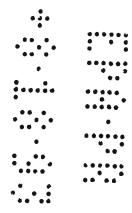
Place the collar around dog's neck, buckle and adjust for proper fit. Cut off close to the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dogs's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Dogs should be examined from time to time and the collar replaced when mature flea or tick populations begin to reappear. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain it is not necessary to remove the collar. Replace when effectiveness diminishes. Deltamethrin 4% Collar may be used in addition to regular collar. Use only one flea collar at a time.

STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

ONE SIZE FITS ALL-TRIM TO SIZE This collar is designed to fit 99% of all

dogs. In the rare instances (for example, well developed St. Bernards or Mastiffs) the collar may be short. If found short for your dog, return to the address on top panel of box for full purchase price refund.



FLEA & TICK COLLAR FOR DOGS

√	GUARANTEED WATER PROOF
✓	KILLS FLEAS FOR 11 MONTHS
. ✓	KILLS TICKS FOR 7 MONTHS
✓	NEW MOLECULE - FIRST COLLAR FORMULATED WITH
	PYRETHROID
✓	ODORLESS
✓	FITS DOGS WITH NECKS UP TO 21"
✓	GUARANTEED OR YOUR MONEY BACK
✓	ONE OF THE LONGEST LASTING FLEA
	& TICK KILLERS AVAILABLE FOR USE
	ON DOGS
√	WETTING WILL NOT IMPAIR COLLARS
	EFFECTIVENESS
✓	MAY BE WORN WITH REGULAR COLLAR
✓	PATENTED INSECTICIDE RELEASE TECHNOLOGY

ACTIVE INGREDIENTS:	BY WEIGHT
Deltamethrin	4.00%
Inert Ingredients	96.00%
	100.00%

* (s)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2-2dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate

CAUTION: Keep out of reach of children

See Side Panel for additional Precautionary Statements

NET CONTENTS: 1 Collar NET WT. 1.1 oz

EPA REG, NO. 432-

EPA EST. NO.

CODE

FLEA & TICK COLLAR FOR DOGS

GUARANTEED 11 Month Flea Killer GUARANTEED 7 Month Tick Killer

Deltamethrin 4% Collar provides full season, 11 month flea killing power (and 7 month protection against ticks). It's guaranteed!

PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS CAUTION:

Do not open protective pouch until ready to use. Do not allow children to handle this collar. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. In case of contact, immediately flush eyes with plenty of water. Immediately get medical attention if irritation persists. Do not use on sick or convalescing dogs. Do not use this collar on puppies less than 12 weeks of age.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, call physician or Poison Control Center. If in eyes, flush with plenty of water. Get medical attention if irritation persists. It is not advisable to use this collar or similar pesticides on puppies less than 12 weeks of age.

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Do not use on sick or convalescing dogs. Other pesticides are not necessary and therefore should not be used on dogs while collar is worn.

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